# EXHIBIT 1

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- - - - - - - - - - - - - - - - - - - - - - - - - - -

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

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DEPOSITION OF RICHARD P. WENZEL, M.D., MSc.

VOLUME I, PAGES 1 - 370

AUGUST 4, 2017

(The following is the deposition of RICHARD P. WENZEL, M.D., MSc., taken pursuant to Notice of Taking Deposition, via videotape, at the Hausfeld law firm, 1700 K Street Northwest, Suite 650, in the City of Washington, District of Columbia, commencing at approximately 9:08 o'clock a.m., August 4, 2017.)





APPEARANCES:

On Behalf of the Plaintiffs:

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ALSO PRESENT:

Ronald M. Huber, Videographer

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PROCEEDINGS

(Witness sworn.)

RICHARD P. WENZEL, M.D., MSc.,

Called as a witness, being first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. ASSAAD:

09:08:59 **Q.** Please state your name.

09:09:00 **A.** Richard Wenzel.

09:09:03 **Q.** And what's your current address?

09:09:05 **A.** 1420 Mosquito Point Road, White Stone, Virginia. Home address you wanted.

09:09:11 **Q.** Yeah. And your business address, if you have one?

09:09:14 **A.** The post office is P.O. Box 901, and again White Stone, Virginia, 22578, so.

09:09:21 **Q.** Are you still affiliated with Virginia Commonwealth University?

09:09:25 **A.** Yep. I'm still teaching. I'm sort of formally retired, but they bring us back every now and then. So I -- I teach.

09:09:33 **Q.** Have you had your deposition taken before?

09:09:36 **A.** Never.

09:09:37 **Q.** This is your first time?

09:09:38 **A.** Yeah.
09:09:39 **Q.** Is this your first time being an expert
09:09:40 witness in a case?
09:09:41 **A.** No. I've been asked questions four other
09:09:44 times. Want to hear about those, or?
09:09:47 **Q.** Four other times?
09:09:48 **A.** Yeah.
09:09:49 **Q.** I'll get to that in a second.
09:09:51 Since this is your first deposition I'm
09:09:53 going to go through the rules very carefully.
09:09:55 **A.** Sure.
09:09:55 **Q.** I'm going to ask you numerous questions. If
09:09:57 you don't understand the question, please let me know.
09:09:59 Fair?
09:09:59 **A.** Yes.
09:10:00 **Q.** If you answer the question, I'll assume that
09:10:01 you understood the question. Fair?
09:10:03 **A.** Yes.
09:10:04 **Q.** At any time you want to take a break, please
09:10:05 let me know. I just ask that you request a break
09:10:07 after you answer a pending question. Fair?
09:10:09 **A.** Yes.
09:10:10 **Q.** And if at any time you want to correct an
09:10:20 answer later on that you gave previously, just please
09:10:23 let me know, we can always go back.





09:10:24 **A.** Good.
09:10:25 **Q.** Today I am representing over 2700 plaintiffs
09:10:28 in a multidistrict litigation, and my goal is to
09:10:30 understand all your opinions today and to understand
09:10:34 what you are going to be testifying at trial.
09:10:36 Do you understand that?
09:10:37 **A.** Yes, I do.
09:10:37 **Q.** So I want a clean record, and I don't want
09:10:39 any -- if there's anything that needs to be corrected,
09:10:42 it's better to correct it today because I will not
09:10:45 have another opportunity -- or I may not have another
09:10:47 opportunity to take your deposition again.
09:10:49 Do you understand that?
09:10:50 **A.** I do.
09:10:50 **Q.** Okay. And also, for the court reporter,
09:10:58 please wait till I finish my question before you begin
09:11:00 answering even though you might know what the question
09:11:02 is, and I'll also wait for your answer before I ask my
09:11:05 next question so that we have a clean record and we
09:11:07 don't upset the wonderful court reporter that's taking
09:11:10 down all our words.
09:11:11 Do you understand that?
09:11:12 **A.** Yes.
09:11:23 **Q.** Now you've been asked to be an expert in
09:11:24 this case; correct?





09:11:25 **A.** That's right.
09:11:25 **Q.** Okay. And you understand as an expert you
09:11:28 are to be objective; correct?
09:11:29 **A.** Yes.
09:11:30 **Q.** Not an advocate for either side. You
09:11:33 understand that.
09:11:33 **A.** I'm not an advocate.
09:11:39 **Q.** Okay. How is it that you became involved in
09:11:41 this case?
09:11:43 **A.** Guessing roughly two and a half years ago a
09:11:47 representative from Greenberg Traurig called me.
09:11:50 **Q.** And who was that?
09:11:52 **A.** And it was Evan Holder.
09:11:55 **Q.** Evan Holden?
09:11:57 **A.** "Holder." "Holder," I think it is.
09:11:58 **Q.** It's Holden.
09:11:59 **A.** Is it? Sorry about that. Been awhile.
09:12:02 **Q.** And that was for the Walton case?
09:12:04 **A.** Yes, it was.
09:12:06 **Q.** And do you know how --
09:12:08 Were you referred to them by someone, or?
09:12:10 **A.** He told me that he had spoken to Michelle
09:12:17 Stevens and Michelle Stevens said I was an infectious
09:12:20 disease person and he asked me if I'd look at the
09:12:23 records.





09:12:24 **Q.** Do you know Michelle Stevens?
09:12:25 **A.** I do.
09:12:26 **Q.** How do you know Michelle Stevens?
09:12:28 **A.** Roughly starting in 2009. As background, I
09:12:34 had been invited to Mexico during the height of the
09:12:38 H1N1 epidemic in April of 2009. It was a fascinating
09:12:43 experience that you don't want to hear about right
09:12:46 now, but about that time I recognized that the
09:12:50 high-risk patients, this is before anybody knew
09:12:52 anything, were obese patients and pregnant patients,
09:12:57 and they were all about 21 years old. I made rounds
09:12:59 in ICUs.
09:13:02 I was asked by, I'm trying to think of her
09:13:07 name, Deborah Gardner from -- who's an administrator
09:13:09 with 3M, if I'd be willing to go to four countries in
09:13:13 South America as part of their infection control
09:13:18 education program. And I think that that first trip I
09:13:23 think also involved Mexico. So that was later on in
09:13:27 2009, and I was very excited because I got a chance to
09:13:32 go back to Mexico to get a follow-up of what I had
09:13:37 observed, and also now it was the winter in South
09:13:41 America so they were undergoing their own beginning
09:13:44 epidemic --
09:13:44 **Q.** I don't mean to interrupt. I don't need
09:13:46 that much detail. I just want to know --

09:13:47 **A.** Okay.
09:13:49 **Q.** -- how and when you met her.
09:13:50 **A.** Okay. So that -- So basically on that trip, she came on the trip and she was a pediatric infectious disease, I was an adult infectious disease. Basically I wound up giving about three lectures per city in each country --
09:14:05 **Q.** So you met her on the trip?
09:14:07 **A.** -- and visited a lot of hospitals there.
09:14:09 **Q.** Okay. You met her on the trip.
09:14:10 **A.** Yeah.
09:14:10 **Q.** Okay. In Mexico. Fair enough.
09:14:12 Have you --
09:14:12 Do you consult for 3M?
09:14:15 **A.** One time I did.
09:14:16 **Q.** At what time? At what period of time?
09:14:18 **A.** Probably three, four years ago they asked me one question, if I would review a meta-analysis related to one of the drapes that they had. So unrelated to the Bair Hugger.
09:14:29 **Q.** Okay. And were you paid for that?
09:14:32 **A.** I was.
09:14:33 **Q.** And how much -- how much per hour were you paid for that?
09:14:36 **A.** Six hundred dollars an hour, and best that I





09:14:38 can remember it was about 10 hours.
09:14:44 **Q.** Do you still keep in touch with Michelle Hulse Stevens?
09:14:47 **A.** No, haven't.
09:14:48 **Q.** You were issued a subpoena in this case. Do you recall that?
09:14:49 **A.** I do.
09:14:57 **Q.** Okay. And you reviewed the subpoena?
09:14:58 **A.** I did.
09:15:00 **Q.** Okay. And the subpoena requested that you produce documents by June 21st, 2017. Do you recall that?
09:15:00 **A.** I do.
09:15:02 **Q.** Did you produce all your documents that were responsive to the subpoena to counsel?
09:15:05 **A.** Yeah. I actually pulled everything, sent it over to counsel and they sent it on.
09:15:06 **Q.** Okay. What's been placed in front of you is a pile of documents that was produced to the plaintiffs today in response to your subpoena that were supposedly due to the plaintiffs on June 21st, 2017.
09:15:06 Are those the documents that you produced to defense counsel in this case responsive to the subpoena?
09:15:09
09:15:11
09:15:14
09:15:16
09:15:40
09:15:43
09:15:49
09:15:53
09:15:55
09:15:58
09:16:00





09:16:01 **A.** I think --
09:16:01 MR. COREY GORDON: I move --
09:16:01 THE WITNESS: Wait. Okay.
09:16:02 MR. COREY GORDON: -- to strike counsel's characterization and want to note for the record that we interposed an objection to certain of the subpoena requests. In the ensuing time period we have re -- revisited those objections, and even though we believe that what -- that the stack of materials is -- would be protected, we have decided to waive that and go ahead and make that available to you, which we did today. So there -- You can now ask your question.
09:16:03
09:16:05
09:16:08
09:16:12
09:16:16
09:16:22
09:16:25
09:16:32
09:16:34
09:16:36 BY MR. ASSAAD:
09:16:36 **Q.** Did you produce those documents to your counsel by June 21st, 2017?
09:16:37 **A.** Yeah. I made the deadline.
09:16:40 **Q.** And would you agree with me that the stack is about a foot high?
09:16:42 **A.** It's a foot high, yeah.
09:16:45 **Q.** Okay. And that contains all of the articles that you reviewed?
09:16:46 **A.** I don't know if it's all of them, but all the ones I underlined for sure.
09:16:47 **Q.** Okay. So many of those documents have
09:16:50
09:16:52
09:16:53
09:16:55





09:16:56 underlines in them?
09:16:58 **A.** Yeah. I'm kind of a nerd and underline a lot of stuff, yeah.
09:17:00 **Q.** Okay. And many of those documents --
09:17:02 MR. BEN GORDON: That was produced, too.
09:17:10 That's also his.
09:17:11 **Q.** Oh I forgot, we have another -- we have another thing to add to the pile so now it's over one foot. You agree?
09:17:12
09:17:15
09:17:17
09:17:18 **A.** Yes, I do.
09:17:18 **Q.** Okay. And so those documents are documents that you have highlights on, or underlines?
09:17:20
09:17:22 **A.** Yes.
09:17:23 **Q.** Documents that you have notes on?
09:17:24 **A.** Yes.
09:17:25 **Q.** You actually have actually handwritten notes on regular paper as well?
09:17:27
09:17:29 **A.** I think I do. I don't --
09:17:31 **Q.** If you look at --
09:17:32 There's a yellow sheet there and a couple other sheets.
09:17:35
09:17:35 **A.** Yeah.
09:17:36 **Q.** Okay. You have -- You have deposition transcripts?
09:17:37
09:17:38 **A.** I think I re --

09:17:38 Yeah. The ones that I looked at, yes.
09:17:41 **Q.** And you spent a lot of time on this case; correct?
09:17:43 **A.** I did.
09:17:44 **Q.** Okay. Do you think it's fair that I get a foot and a half set of documents on the day of your deposition to review when I only have seven hours to take your deposition?
09:17:53 MR. COREY GORDON: I object to the question, lack of foundation. Also calls for a legal conclusion.
09:17:58 As I noted, we interposed an objection. That's not Dr. Wenzel's decision. We also made the decision, the lawyers, to produce these in spite of what we believe to be a valid objection.
09:18:11 MR. ASSAAD: Objection noted.
09:18:12 **Q.** Do you think it's fair, as a layman, that you, who spent over 300 hours on your report and reviewed all these documents, that I get a foot and a half or a foot and a quarter of documents on the day of your deposition?
09:18:24 MR. COREY GORDON: Object to the form of the question, lack of foundation.
09:18:27 **Q.** You may answer.
09:18:29 **A.** So my view was to get the documents to the





09:18:32 law offices, and after that it's their decision.
09:18:36 **Q.** I mean, do you think it'd be fair if I gave you a foot and a half of documents on the day of the deposition and expect you to answer questions on it?
09:18:42 MR. COREY GORDON: Same objections.
09:18:44 **Q.** "Yes" or "no"? Do you think it's fair?
09:18:45 **A.** Well --
09:18:45 MR. COREY GORDON: Same objections.
09:18:46 MR. ASSAAD: It's a simple question. It's a simple question.
09:18:48 MR. COREY GORDON: Wait, wait.
09:18:48 MR. ASSAAD: I got your objection. You said "same objection." No speaking objections.
09:18:53 **Q.** You may answer the question.
09:18:53 MR. COREY GORDON: Gabe -- Gabe, let me stop you right now. If we're going to have another episode like we did last week --
09:18:58 MR. ASSAAD: You call the judge. You can call the judge. You produced a foot and a half of documents on the day of deposition. I am happy with that. You want to do that?
09:19:03 (Interruption by the reporter.)
09:19:04 MR. ASSAAD: I'm just asking if it's -- if he would think it would be fair if I gave him a foot and a half of documents on the day of deposition.





09:19:09 MR. COREY GORDON: As a courtesy to the court reporter, if no one else, I am simply asking you, Mr. Assaad, to try to chill out a little bit and wait until either Dr. Wenzel has finished his answer, I have finished my objection before you launch into whatever you want to -- want to speak about.
09:19:29 MR. ASSAAD: I will give you a continuing objection that my line of questioning is objectionable.
09:19:36 MR. COREY GORDON: No. I'm not going to take a continuing objection. I will interpose objections --
09:19:41 MR. ASSAAD: Okay.
09:19:41 MR. COREY GORDON: -- as I see fit. I just ask you to give me and the witness and the court reporter --
09:19:43 MR. ASSAAD: I --
09:19:46 MR. COREY GORDON: -- the courtesy of not talking -- trying to talk over us. We -- We went through an unpleasant --
09:19:51 MR. ASSAAD: I got -- I got -- I got it, Corey.
09:19:52 MR. COREY GORDON: You're doing it right now, Gabe.
09:19:53 MR. ASSAAD: Well Corey, you don't need to





09:19:56 waste time. We don't have a lot of time, we have a huge expert report to go through that he spent 300 hours on.
09:20:01 **Q.** I'm just asking if he thinks it would be fair if I gave him a foot and a half of documents on the day of his deposition to answer questions on.
09:20:08 MR. COREY GORDON: My objections are the same.
09:20:10 **A.** Again, what I would say is I met my obligation to get the documents to the legal firm on time.
09:20:17 **Q.** So you don't want to answer my question, is that --
09:20:22 **A.** No, I mean, I think it would be -- if you gave me this to read in one day, yeah, that would be challenging.
09:20:28 **Q.** Okay. It would be challenging; correct?
09:20:29 **A.** Yes.
09:20:31 **Q.** Okay. I mean, from --
09:20:32 I mean, you wouldn't expect to give one of your students a foot and a half of documents and to answer questions on it in seven -- in seven hours; would you?
09:20:35
09:20:38
09:20:41
09:20:43 **A.** No, probably not.
09:20:43 **Q.** Okay. Are all the documents that you

produced to counsel listed in your expert report?
**A.** I think so.
**Q.** Okay. You do understand that today you're under oath; correct?
**A.** I do.
**Q.** And that's under penalty of perjury; correct?
**A.** That's correct.
**Q.** If you realize that anything in your report is incorrect or wrong, this is the time to inform us. Do you understand that?
**A.** I do.
**Q.** Okay. Now it's my understanding, from reading your report, that you don't believe that infections can be caused by airborne contaminants in the operating room. Is that true?
**A.** I don't think that's exactly what I said. I think the key element of my report is I couldn't find evidence linking the Bair Hugger to harm, and then I went through a great deal of papers to show that I think most infections, the vast majority, come from the patient's own microbiome. I'm not sure that's your question, but that...
**Q.** So you -- it's your opinion that most of the infections that occur during a total knee or total hip





arthroplasty come from the patient's own biome, microbiome.
**A.** Yes, I do.
**Q.** Okay. And that's based on research that you reviewed?
**A.** Research that I reviewed, yeah.
**Q.** Okay. And we'll get to that soon.
And when we're talking about infections during total hip/total knee arthroplasty we're talking about any type of infection, not infections that may be caused by a Bair Hugger, correct, that are caused by the human biome?
**A.** I'm not sure. The question again?
**Q.** Well before you limited to your -- your opinion that the Bair Hugger doesn't cause infections. Do you recall that?
**A.** Yeah. What I said is I couldn't find evidence that would link the Bair Hugger to any link to infections.
**Q.** Okay. My question is: With respect to just total hip and total knee, irrespective of the source of the -- or what may or may not cause the infections, it's your opinion that the majority of those infections are caused by bacteria on the patient's own biome.





**A.** I do, yes.
**Q.** Okay. Is it my understanding that the majority of the time you spent on formulating your opinions was doing a literature review?
**A.** Yes.
**Q.** Okay. You didn't do any biological testing; correct?
**A.** That's correct.
**Q.** You looked at no internal 3M documents; correct?
**A.** That's correct.
**Q.** Okay. You didn't do any particle testing; correct?
**A.** That's correct.
**Q.** Okay. In fact you haven't -- you didn't do any type of original testing.
**A.** Not related to this case.
**Q.** Okay. Your report is largely a recitation and cri -- of critiques of various peer-reviewed studies; correct?
**A.** It's my review of the peer-reviewed studies, and my conclusions based on the data that I saw and my interpretation of the data.
(Wenzel Exhibit 1 marked for identification.)





BY MR. ASSAAD:
**Q.** What's been marked as Exhibit 1 is a copy of your report. Do you agree with me that that is a complete copy of your report?
**A.** It looks like it.
**Q.** Okay. And have you had a chance to review your report before today's deposition?
**A.** Yes, I have.
**Q.** Okay. You've reread your entire report before today's deposition?
**A.** I have.
**Q.** Okay. And you --
Is there anything that you want to change in your report before we begin?
**A.** I don't think so, but we'll see.
**Q.** Sitting today, these are your complete opinions and all of the sources that you rely upon to formulate your opinions as of June 2nd, 2017 when you submitted this report.
**A.** Are there other articles out there, are you asking, --
**Q.** No.
**A.** -- that I might have thought about since then, or?
**Q.** Well I'm asking about articles and

literature that you rely upon.
**A.** Yeah.
**Q.** And that you've cited and have reviewed to support your opinions in your report. They're all contained in this report of Exhibit 1; correct?
**A.** Either here or the materials that I sent to you, yeah.
**Q.** Okay.
MR. COREY GORDON: And I want -- so you can ask him about it, I want you to know we are going to ask him to offer an opinion of the valid -- the validity of the recently published Scott Augustine thing.
MR. ASSAAD: I understand that, but I think before I'm going to ask him any questions on that he should file a supplemental report so I can prepare, and to prepare what his opinions are going to be and we can come back and take his deposition.
MR. COREY GORDON: So will you agree to that with your experts as well, who've rendered -- who've supplemented their opinions based on the newly published Augustine whatever it is?
MR. ASSAAD: We'll you've already asked them questions on it, but I will consider it.
BY MR. ASSAAD:





**Q.** Now let's turn to page 73 of your report. You noted on the bottom of page 73, on the third paragraph from the bottom, "Dr. Jarvis' deposition is superficial and wanting."
Do you see that?
**A.** I do.
**Q.** Okay. What deposition did you read by June 2nd, 2017?
**A.** I -- I read his deposition. Is that what you're asking me?
**Q.** You signed this on June 2nd, 2017; correct? Next page, sir.
**A.** Yeah. No, I see that.
**Q.** Okay. What deposition did you have of Dr. Jarvis that you want to criticize him as being superficial and wanting?
**A.** Yeah, I don't know why the days don't match.
**Q.** Well did you not check your report to see if it was accurate?
**A.** I did.
**Q.** Okay. Do you agree with me that this is not accurate?
**A.** Well I agree that I have the 2nd written down there, and I don't know why -- I did read Dr. Jarvis's deposition, and I thought it was at the time





that I did this report.
**Q.** Well, sir, for the -- his deposition was after June 2nd, 2017.
**A.** When was his deposition?
MS. ZIMMERMAN: Last Tuesday.
**Q.** Last Tuesday.
**A.** Oh, that's probably his report, then, that I'm talking about, if that's true.
**Q.** So you're saying this is not accurate.
**A.** I'm saying that I should have had the word "report" there.
**Q.** Instead of "deposition"?
**A.** Instead of "deposition."
**Q.** Okay. So you agree that's a mistaken your report.
**A.** I agree and apologize.
**Q.** Okay. And so you want to criticize Dr. Jarvis to say that his -- that his opinions are superficial and wanting before you even had a chance to read his deposition?
**A.** I saw it based on his report.
**Q.** Okay. Page 74, third paragraph. You indicate that "Dr. Samet's deposition is uncritical and wanting." It seems like you like the word "wanting"; correct?





**A.** I did say the word "wanting" and again --
**Q.** What does "wanting" mean to you?
MR. COREY GORDON: Gabe, let him finish his answer. You're going to -- You're starting it again.
**A.** Well again, I thought it was very uncritical. You want me to tell you why about both of these people?
**Q.** No. So you thought it was uncritical and wanting, but you didn't have a chance to read his deposition by that date; correct?
**A.** No. This -- I should have said --
**Q.** Okay.
**A.** -- his report. A mistake.
**Q.** Okay. Another mistake; correct?
**A.** Yes.
**Q.** Okay. So now you agree that there are mistakes in your report.
**A.** In terms of those words, yes.
**Q.** Okay. And there may be some others that we'll point out later on.
**A.** Don't know.
MR. COREY GORDON: Object to the form of the question, move to strike.
**Q.** Now do you agree that all the articles that you cited are authoritative?

MR. COREY GORDON: Object to the form of the question.
**Q.** In your report of Exhibit 1?
**A.** If I cited them they gave some insight, I think, in ter --
**Q.** So you'd rely --
**A.** Huh?
**Q.** So you'd rely on -- on the articles that you cited.
MR. COREY GORDON: Object to --
**A.** Some much more than others.
THE WITNESS: I'm sorry.
MR. COREY GORDON: Object to the form of the question.
MR. ASSAAD: Basis?
MR. COREY GORDON: "Reliance" is a legal term, and if you want to ask him what he, as a scientist, was doing, that's fine. But you're -- you're -- you're trying to, you know, as you just did, try to --
MR. ASSAAD: I got your objection.
MR. COREY GORDON: -- impose a legal term.
MR. ASSAAD: I got your objection.
**Q.** Do you know what the term "rely" means?
**A.** In legal terms, no.





**Q.** How about in scientific terms?
**A.** Yeah. Scientific terms I would say, yeah, it's credible evidence.
**Q.** Okay. And do you know what "authoritative" means?
**A.** Usually by someone who's thought to be reputable.
**Q.** Okay. And you understand when I refer -- if I ask you if an article is authoritative?
**A.** Yeah. You might want to -- I would probably want to add some weight to that or not, some more weighty than others in terms of the force of the data available.
**Q.** It's my understanding that you have cited, I mean, last time I counted, between -- in your -- in your report, like, over 90 articles in your -- in your expert report; correct?
MR. COREY GORDON: Objection, --
**A.** I don't know.
MR. COREY GORDON: -- lack of foundation.
**A.** I don't know how many there were. There were a lot.
**Q.** You've read your report; correct?
**A.** I have.
**Q.** And there are many -- you cite to many





different articles; correct?
**A.** I do.
**Q.** And it's my understanding that you read those articles completely; correct?
**A.** If I cited it, I read those articles.
**Q.** You didn't just read the abstract.
**A.** I did not read just the abstract.
**Q.** Okay.
(Wenzel Exhibit 2 marked for identification.)
BY MR. ASSAAD:
**Q.** What's been marked as Exhibit 2 is a list of articles that -- and documents that you considered or reviewed; is that correct?
**A.** That's correct.
**Q.** But they may not be cited in your report; correct?
**A.** I think that's true.
**Q.** Okay. Do you consider all of the articles in Exhibit 2 to be authoritative?
MR. COREY GORDON: Object to the form of the question.
**A.** I don't know if they're authoritative. They're -- They're articles I read related to the case.





**Q.** Did you rely on them in formulating your opinions?
**A.** Some of them I didn't actually use in my report.
**Q.** That wasn't my question, sir.
Did you rely -- Did you rely on them in formulating your opinions, whether or not you cited them in your report?
MR. COREY GORDON: Same objections.
**A.** Yeah, for the most part I think that's true.
**Q.** The answer to my question is "yes."
**A.** Yes.
**Q.** Okay. Going to Exhibit B, it seems like you received the report of -- the expert report of Michael Buck. Do you see that?
**A.** Where is that?
**Q.** First line.
**A.** Yeah.
**Q.** But you offer no criticisms in your report of Michael Buck; correct?
**A.** No. I didn't spend much time on that, no.
**Q.** So the answer to my question is you didn't offer any criticisms of Michael Buck in your report; correct?
**A.** I did not. That's correct.

09:33:35 **Q.** Okay. You also looked at the report of Dr. Said Elghobashi; correct?
09:33:37 **A.** Yes.
09:33:38 **Q.** In your report you didn't offer any criticisms of Dr. Elghobashi in your report; correct?
09:33:42 **A.** That's true.
09:33:43 **Q.** Did you even understand his report?
09:33:45 **A.** It was way over my head.
09:33:47 **Q.** Okay. I understand that you criticize Dr. Jarvis as being -- I'd like to use the words you
09:33:51 used -- "superficial and wanting"; correct?
09:33:56 **A.** That's correct.
09:34:05 **Q.** Okay. And you also criticized Dr. Jonathan
09:34:06 Samet in your report as being "wanting" as well;
09:34:12 correct?
09:34:14 **A.** That's correct.
09:34:15 **Q.** Did you have any criticism of Dr. Holford's
09:34:16 report?
09:34:18 **A.** No.
09:34:20 **Q.** Why not?
09:34:20 MR. COREY GORDON: Object to the form of
09:34:22 the question.
09:34:23 **A.** I thought he was helpful, actually.
09:34:23 **Q.** Have you read his --
09:34:27 (Interruption by the reporter.)





09:34:28 **Q.** Did you rely on his opinions in formulating
09:34:32 your opinions?
09:34:34 **A.** In -- In part, where he talked about the
09:34:36 changing rates, for example, over time during the Bair
09:34:41 Hugger period, when he showed the high rates at that
09:34:45 hospital compared to the rest of the U.K. hospitals in
09:34:48 the same trust. There were a couple of things like
09:34:52 that that made me even more skeptical of the articles
09:34:59 that were focusing on --
09:35:00 **Q.** You're talking about the McGovern article.
09:35:02 **A.** McGovern article.
09:35:03 **Q.** So would you agree -- would you defer to Dr.
09:35:06 Holford with respect to his analysis of the McGovern
09:35:08 article?
09:35:09 MR. COREY GORDON: Object to the form of
09:35:10 the question.
09:35:10 **A.** No, I don't think I would defer to him at
09:35:12 all. I think I have my own opinion.
09:35:15 **Q.** Okay. But you relied on some of the
09:35:16 information you obtained from his report in
09:35:19 formulating your opinions.
09:35:19 **A.** A little bit of that, yes.
09:35:22 **Q.** Okay. With respect to Dr. Borak, do you
09:35:25 have any criticism of his report?
09:35:26 **A.** No. I thought he did a good job.





09:35:28 **Q.** Okay. Did you rely on any information in
09:35:33 Dr. Borak to formulate your opinions?
09:35:38 **A.** Yes. I -- In his report -- I want to make
09:35:43 sure I don't mix up his report with his deposition. I
09:35:53 think -- Yeah. His -- His focus on the rivaroxaban
09:35:58 issue, I -- I thought was very helpful, added to what
09:36:02 I thought was going on.
09:36:04 **Q.** Okay. So did you rely on information in his
09:36:11 report to formulate your opinions, some of your
09:36:14 opinions?
09:36:14 **A.** Perhaps.
09:36:16 **Q.** Is that a "yes" or a "no"?
09:36:17 **A.** Yeah, I think it's a yes, but I -- you know,
09:36:19 I can't exactly remember what parts.
09:36:36 **Q.** You don't consider yourself an expert in
09:36:40 hypothermia; do you?
09:36:43 MR. COREY GORDON: Object to the form of
09:36:44 the question.
09:36:44 **A.** No, in the sense that where hypothermia
09:36:48 inter -- interfaces with infectious disease I think I
09:36:51 know a lot, yes.
09:36:51 **Q.** What research have you done with
09:36:53 hypothermia?
09:36:53 **A.** I've done no direct research with it.
09:36:55 **Q.** So you're just basically relying on





09:36:58 literature review to -- for your understanding of
09:36:59 hypothermia as related to surgical-site infections.
09:37:02 **A.** Well with the background in infectious
09:37:04 diseases and interest in hospital-acquired infections.
09:37:07 If that's part of the mix, yes.
09:37:08 **Q.** Well you graduated from medical school in
09:37:15 1965; correct?
09:37:17 **A.** That's correct.
09:37:17 **Q.** And a lot of the research regarding the
09:37:19 effects of hypothermia on -- and its effect on
09:37:25 surgical-site infections was much after 1965. Do you
09:37:27 agree?
09:37:28 **A.** No question. Yes.
09:37:30 **Q.** Okay. So a lot of the --
09:37:31 I mean, you have done no research on that
09:37:33 issue independently; correct?
09:37:34 **A.** That's correct.
09:37:35 **Q.** Okay. And you've done no studies on that;
09:37:36 correct?
09:37:37 **A.** No studies.
09:37:38 **Q.** Okay. So you agree that most of the
09:37:40 information that you've obtained was through
09:37:43 peer-reviewed articles that other people have done in
09:37:46 the area; correct?
09:37:47 **A.** That's correct.

09:37:47 **Q.** Okay. And you'd agree with me that the two
09:37:50 leading people dealing with the effects of hypothermia
09:37:53 in the world are Dr. Andrea Kurz and Dr. Daniel
09:37:58 Sessler; correct?
09:37:59 **A.** Yes.
09:38:01 **Q.** Okay. So you would defer to them with
09:38:01 respect to the effects of hypothermia on surgical-site
09:38:04 infections; correct?
09:38:04 **A.** I don't know --
09:38:04 MR. COREY GORDON: Object to the form of
09:38:06 the question.
09:38:06 **A.** -- if I'd defer to them, no.
09:38:08 **Q.** So you wouldn't defer to a doctor that has
09:38:11 spent their entire life doing research on an issue,
09:38:15 that -- that has published tens of articles on that
09:38:20 issue, has given talks around the world on that issue,
09:38:26 and continues to do research on that issue, you
09:38:29 wouldn't defer to them on issues of hypothermia?
09:38:32 MR. COREY GORDON: Object to the form of
09:38:33 the question.
09:38:34 **A.** What I would do is look at what they have
09:38:36 written and see if that comports with all the other
09:38:39 data that are out there, and look at their articles
09:38:41 themselves so I would formulate an opinion. I'm not
09:38:46 intimidated by the whole raft of research that someone





09:38:50 else has done to say I'm not going to have a thought
09:38:52 on it.
09:38:54 **Q.** So you wouldn't defer to Dr. Sessler or Dr.
09:38:56 Kurz with respect to hypothermia and surgical-site
09:38:58 infections.
09:38:58 **A.** Not necessarily. I'd like to know exactly
09:39:00 what you're getting at so I can comment on it.
09:39:03 **Q.** Well who else out there has done research
09:39:08 with respect to hypothermia and the incident of
09:39:11 surgical-site infections?
09:39:13 **A.** Well I looked at two clinical trials, I
09:39:19 cited those both in my report. And Melling was the
09:39:24 second one after Kurz. I cited Madrid's recent
09:39:29 meta-analysis. There's also an earlier meta-analysis,
09:39:34 I cited the author, and -- and that came in a
09:39:38 publication in AORN, Eileen Scott's. I cited six
09:39:46 cohort studies of people who've done work in
09:39:50 hypothermia. I cited a case-control study about
09:39:56 hypothermia and infections. I cited eight studies
09:40:03 looking for anything that the Bair Hugger may have
09:40:08 done in terms of colony-forming units, which would be
09:40:14 maybe a step in the pathway of infections.
09:40:18 **Q.** Sir, I'm not -- I'm not talking about Bair
09:40:20 Hugger. I'm talking about hypothermia and the
09:40:22 incidence of SSI.





09:40:24 **A.** Yeah. And I've cited the -- well SSI --
09:40:29 Yeah.
09:40:29 So I think I've given you a -- a number of
09:40:33 papers to look at that.
09:40:34 **Q.** Okay. You've never spoken on the issue of
09:40:46 hypothermia and effects of surgical-site infections;
09:40:50 correct?
09:40:51 **A.** I've spoken on surgical-site infections
09:40:53 where I've cited work on hypothermia, but I haven't
09:40:58 just given a talk just hypothermia.
09:41:00 **Q.** Okay. Have you read the deposition of Dr.
09:41:04 Sessler?
09:41:05 **A.** Yeah. I don't remember that very well, but
09:41:07 yeah.
09:41:07 **Q.** Do you remember the deposition of Andrea
09:41:08 Kurz?
09:41:09 **A.** I do.
09:41:10 **Q.** Okay. And you read that one?
09:41:11 **A.** Yes.
09:41:11 **Q.** Okay.
09:41:11 MR. ASSAAD: Mark this as Exhibit 3.
09:41:11 (Wenzel Exhibit 3 marked for
09:41:51 identification.)
09:41:51 MR. ASSAAD: I don't have a copy for you.
09:41:53 MR. COREY GORDON: That's fine. Just note





09:41:53 that that came out of the box of materials.
09:41:56 MR. ASSAAD: I was about to say that.
09:41:57 MR. COREY GORDON: That's fine.
09:41:58 BY MR. ASSAAD:
09:41:59 **Q.** Exhibit 3 came out of the documents that
09:42:01 were produced today; correct, doctor?
09:42:02 **A.** I think that's right, yes.
09:42:03 **Q.** Okay. Where'd you obtain that document
09:42:05 from?
09:42:07 **A.** This one I think I got from counsel, but I'm
09:42:10 not sure.
09:42:10 **Q.** So is that the only document of Exhibit 3
09:42:12 that you obtained from counsel?
09:42:15 **A.** No.
09:42:18 **Q.** What other document --
09:42:19 **A.** Are there other documents, you mean, that
09:42:21 they may have sent to me to read?
09:42:23 **Q.** Yes.
09:42:23 **A.** Is that what you're asking?
09:42:24 **Q.** Well Is that -- Let me rephrase.
09:42:26 Is that the only internal document, like
09:42:28 non-peer-reviewed literature that you received from
09:42:30 counsel?
09:42:30 MR. COREY GORDON: Object to the form of
09:42:31 the question.

09:42:32 **A.** Not sure, but probably.
09:42:33 **Q.** Okay. So you didn't receive any internal
09:42:36 testing of the Bair Hugger from 3M?
09:42:38 **A.** No.
09:42:39 **Q.** You didn't receive any --
09:42:41 Did you receive any of the computational
09:42:48 fluid dynamics studies that were done internally by
09:42:52 3M?
09:42:52 **A.** No.
09:42:53 **Q.** Did you receive any of the schlieren studies
09:42:56 that were done internally by 3M?
09:42:58 **A.** No.
09:42:58 **Q.** Did you see --
09:42:59 Did you get any of the calculations done
09:43:03 with respect to whether or not the Bair Hugger
09:43:05 disrupts unidirectional flow that was done internally
09:43:11 by 3M?
09:43:12 **A.** No.
09:43:12 MR. COREY GORDON: Object to the form of
09:43:13 the question.
09:43:14 MR. ASSAAD: Basis?
09:43:15 MR. COREY GORDON: Assumes facts not in
09:43:18 evidence, and -- and the predicate of the question is
09:43:22 actually contrary to evidence.
09:43:23 MR. ASSAAD: Okay.





09:43:25 **Q.** Did you receive any of the -- Strike that.
09:43:40 Did you see the computational fluid dynamic
09:44:05 videos perfor -- prepared by Dr. Elghobashi?
09:44:09 **A.** Was that a Science Day? I can't remember --
09:44:11 **Q.** No.
09:44:11 **A.** -- whether he had one. Then I probably
09:44:13 didn't see it.
09:44:14 **Q.** Did you see the videos prepared by Dr.
09:44:17 Abraham?
09:44:17 **A.** I think he had that at Science Day. That's
09:44:20 all I saw, yes.
09:44:22 **Q.** Okay. But my understanding is because your
09:44:27 opinion is that most of the infections that cau --
09:44:30 most of the bacteria that causes surgical-site
09:44:32 infections is on the patient's flora, that airflow in
09:44:37 the operating room is -- is not that -- is not as
09:44:43 important as other areas with respect to infection.
09:44:46 MR. COREY GORDON: Object to the form of
09:44:48 the question.
09:44:48 **A.** What I would say is that if you're looking
09:44:50 for the reservoir of the organisms causing
09:44:54 surgical-site infections, my opinion is that they come
09:44:58 from the patient the vast majority of time.
09:45:01 **Q.** When you say "vast majority," can you give
09:45:02 me a percentage?





09:45:03 **A.** Well in my report I've said somewhere
09:45:05 between 70 and 90 just based on the data that we have
09:45:09 already.
09:45:10 **Q.** Okay. And that is because, based on your
09:45:15 opinion that if a surgical-site infection occurs that
09:45:25 it's -- it's most likely patient flora and not from
09:45:29 airborne contamination.
09:45:30 MR. COREY GORDON: Object to the form of
09:45:31 the question.
09:45:31 **A.** It's based on my opinion, which is based on
09:45:35 review of the literature that looks at the microbiome
09:45:39 and the influence of the microbiome on the organisms
09:45:44 causing surgical-site infections.
09:45:49 Is that clear, or let me know if you --
09:45:50 **Q.** Well no. I'm just trying to understand your
09:45:53 opinion --
09:45:53 **A.** Yeah.
09:45:53 **Q.** -- and just to sum it up.
09:45:53 **A.** Sure.
09:45:54 **Q.** Your opinion is that the most likely cause
09:45:56 of a surgical-site infection is the pla -- the
09:45:59 patient's flora.
09:46:00 **A.** Yes.
09:46:01 **Q.** Okay. And you don't believe that the --
09:46:09 that the air quality of an operating room causes a





09:46:18 significant risk of surgical-site infection.
09:46:22 MR. COREY GORDON: Object to the form of
09:46:23 the question.
09:46:24 **A.** Well I'm not sure what you mean by
09:46:25 "significant risk," but I think -- I mean, I belie --
09:46:30 I'm interested in infection control, no question, and
09:46:33 I would love the air to be as clean as possible. And
09:46:36 the question really gets to the heart of this is does
09:46:40 air influence the infections or the infection rate,
09:46:48 and it's hard to find a lot of data to support that.
09:46:51 **Q.** Well --
09:46:52 **A.** I -- I don't want to say it's a total
09:46:53 impossibility. I'm one of those guys, you'll ask me a
09:46:56 lot of questions, I won't say "never" or "always."
09:46:59 **Q.** Well let's do it this way to make things
09:47:01 easier. I'm asking for your opinion within a
09:47:05 reasonable degree of medical probability. Okay?
09:47:06 **A.** Umm-hmm.
09:47:07 **Q.** I'm not asking for a hundred percent
09:47:08 certainty.
09:47:09 **A.** Yeah.
09:47:09 **Q.** You understand that?
09:47:10 **A.** Yeah.
09:47:10 **Q.** So it's my understanding that your opinion
09:47:12 is that the mo -- that -- that more likely than not

09:47:16 the air quality in an operating room does not cause a
09:47:19 significant risk in surgical-site infections.
09:47:21 MR. COREY GORDON: Object to the form of
09:47:22 the question.
09:47:22 **A.** I don't know that I would phrase it that
09:47:23 way.
09:47:24 What I would say is most -- the origin, in
09:47:27 other words, the reservoir of the organisms causing
09:47:30 surgical-site infections is the vast majority are
09:47:33 going to be in the patient, they're endogenous, in my
09:47:38 opinion. I -- You know, I want the air to be as pure
09:47:40 as possible. I think there's always a possibility
09:47:44 that air is involved in surgical-site infections. I
09:47:48 think the information that we'd love to have to answer
09:47:52 your question is -- is still not out there clear. And
09:47:55 the reason, in part, if you want to look at laminar
09:47:59 airflow. So right after the Lidwell's really
09:48:03 interesting study, you know, heart and lung, number of
09:48:06 patients, 8,000 patients, randomized, you know, a lot
09:48:11 of hospitals began to then rely on laminar airflow.
09:48:15 So what happened then? So you had Brandt's study, you
09:48:19 know, the total review, and then you had Gastmeier's
09:48:23 review, and then you had a review by Hooper for the
09:48:28 New Zealand and the follow-up New Zealand; four cohort
09:48:33 studies, 300,000 patients, and what they found





09:48:37 actually was the infection rates were a little higher
09:48:41 if you had laminar airflow.
09:48:43 Follow that up. More recently Bischoff has
09:48:47 done a big meta-analysis published in *Lancet*, and what
09:48:51 he showed was in fact with 14 studies, hips and knees,
09:48:57 there is no real improvement when you add all those
09:49:02 data as well from the meta --
09:49:03 **Q.** Can I ask you a question real quick?
09:49:06 **A.** Hmm?
09:49:06 **Q.** Can I ask you a question real quick?
09:49:07 **A.** Yeah.
09:49:08 **Q.** What percentage of hospitals in the United
09:49:10 States use laminar airflow?
09:49:11 **A.** I don't know what the answer is. I don't
09:49:12 think it's the majority.
09:49:14 **Q.** I mean, have you ever been in an operating
09:49:15 room in the United States that has laminar airflow?
09:49:18 **A.** Don't think so.
09:49:20 **Q.** Do you know what laminar airflow is?
09:49:22 **A.** Unidirectional filtered air.
09:49:24 **Q.** That's your understanding of laminar
09:49:25 airflow?
09:49:25 **A.** Yeah. I'm not an expert in laminar.
09:49:27 **Q.** Okay. So when you read studies that discuss
09:49:30 laminar airflow and turbulent airflow, --





09:49:33 **A.** Yeah.
09:49:33 **Q.** -- do you -- don't you think it's important
09:49:35 to understand the difference?
09:49:37 **A.** Yeah.
09:49:37 **Q.** Okay.
09:49:37 **A.** I think I do.
09:49:38 **Q.** So what --
09:49:38 So your difference is one is unidirectional,
09:49:40 and the --
09:49:41 And what's "turbulent" then?
09:49:42 **A.** Turbulent is where there's no effort to sort
09:49:46 of compartmentalize the air either from the side or
09:49:49 from the top that laminar flow is trying to push down
09:49:54 the particles or -- in one way or another.
09:49:59 **Q.** So what's turbulent, then? Where is the air
09:50:01 coming from?
09:50:02 **A.** Turbulent they don't have that. The air is
09:50:05 ambient air coming through a filter that's in the
09:50:07 operating room.
09:50:09 **Q.** But where are the -- where is -- where is
09:50:10 the vents?
09:50:12 MR. COREY GORDON: Objection, lack of
09:50:13 foundation.
09:50:13 **A.** I don't know.
09:50:14 **Q.** I mean, doctor, you agree with me that if





09:50:17 you're going to criticize articles and use it to
09:50:20 formulate your opinions that you should have --
09:50:21 especially discussing laminar flow and turbulent flow,
09:50:25 you should have a good understanding of what the
09:50:27 difference is. Don't you agree?
09:50:28 MR. COREY GORDON: Object to the form of
09:50:29 the question.
09:50:29 **Q.** Don't you agree, doctor?
09:50:30 **A.** I'd love to know more about laminar flow,
09:50:33 but I've -- I've cited 300,000-plus patients who
09:50:37 undergo laminar flow, and then I've cited a
09:50:41 meta-analysis recently.
09:50:43 **Q.** But would it make any difference if 99
09:50:45 percent of the hospitals in the United States don't
09:50:47 use laminar flow?
09:50:49 MR. COREY GORDON: Object to the form of
09:50:49 the question.
09:50:50 **A.** I don't even understand that question.
09:50:51 **Q.** Well you --
09:50:53 Do you know what percentage of hospitals in
09:50:54 the United States use laminar flow?
09:50:56 **A.** No, I don't. I thought it was a minority.
09:50:58 **Q.** Do you think if air comes from the ceiling
09:51:00 that it's laminar flow?
09:51:01 MR. COREY GORDON: Object to the form --

09:51:02 **A.** No, not necessarily.
09:51:02 MR. COREY GORDON: -- of the question, lack
09:51:02 of foundation.
09:51:04 **Q.** Okay. So why would you compare laminar flow
09:51:08 to turbulent flow in a case in the United States of
09:51:10 America where most of the patients are in turbulent
09:51:15 airflow operating rooms in your report, if it's
09:51:18 completely irrelevant?
09:51:20 MR. COREY GORDON: Object to the form of
09:51:20 the question.
09:51:21 **A.** No. You asked -- You asked me a question
09:51:23 about the importance of air, and then I went back to
09:51:28 say -- and you said, is it not important or important,
09:51:30 something along that line. Then I went back to talk
09:51:33 about Lidwell's study that stimulated the really
09:51:37 international push for laminar flow, and --
09:51:41 **Q.** I understand the studies.
09:51:42 MR. ASSAAD: I'm not asking for him to
09:51:44 describe the studies, Corey. We're going to have a
09:51:45 long day, we're going to --
09:51:46 MR. COREY GORDON: No. Let's make
09:51:47 short-circuit. Are you prepared to stipulate that
09:51:50 studies on laminar airflow are irrelevant to this
09:51:51 case?
09:51:51 MR. ASSAAD: No. No. But when it comes to





09:51:55 infection -- I'm just ask -- I'm trying to see if
09:51:58 understands what laminar flow is.
09:51:59 MR. COREY GORDON: Okay. Well you've asked
09:52:00 him that.
09:52:00 MR. ASSAAD: Well he's --
09:52:00 BY MR. ASSAAD:
09:52:01 **Q.** You're criticizing laminar flow as compared
09:52:06 to turbulent flow.
09:52:06 **A.** Yeah.
09:52:06 **Q.** You do understand we're in the United States
09:52:07 of America and this case is here; correct?
09:52:09 **A.** Pardon me?
09:52:09 **Q.** The case is here in the United States of
09:52:11 America.
09:52:11 **A.** Yes, they are.
09:52:11 **Q.** Okay.
09:52:11 **A.** Yeah.
09:52:13 **Q.** And if you're looking at infection rates
09:52:15 with respect to what happens in the United States, if
09:52:20 the majority of the United States operating rooms do
09:52:22 not -- do not contain laminar flow, then the issue
09:52:24 between laminar and turbulent is irrelevant; correct?
09:52:27 **A.** Well --
09:52:28 MR. COREY GORDON: Object to the form of
09:52:29 the question, also lack of foundation.





09:52:30 **A.** You know, I'm trying to respond to the
09:52:32 question of how important air is, and --
09:52:33 **Q.** I'm talking about laminar and turbulent,
09:52:35 sir, --
09:52:36 **A.** No, I understa --
09:52:37 **Q.** -- I'm not talking about --
09:52:38 **A.** No. I understand.
09:52:38 So what I'm saying is if you want to look at
09:52:41 the difference, laminar flow clearly has been shown to
09:52:43 decrease particles. And the question is does
09:52:46 decreased particles really relate to the endpoint
09:52:50 surgical-site infections. So I've cited data from
09:52:53 four large cohorts, over 300,000 patients, and then an
09:52:58 additional 14 patients in a meta-analysis by Bischoff,
09:53:03 and an accompanying editorial by Weinstein that talks
09:53:08 about you don't need laminar flow. So that's --
09:53:16 that's a lot of data.
09:53:17 **Q.** Do you know what the velocity of air is in a
09:53:20 laminar flow system in Australia?
09:53:22 **A.** I don't know what the velocity is in
09:53:24 Australia.
09:53:25 **Q.** In the United Kingdom?
09:53:27 **A.** No.
09:53:27 **Q.** Do you know what it is in New Zealand?
09:53:29 **A.** No.





09:53:30 **Q.** Okay. Don't you think the velocity of air
09:53:32 has a lot to do with how air flows in an operating
09:53:35 room?
09:53:35 **A.** May well, --
09:53:35 MR. COREY GORDON: Object to the form of
09:53:36 the question.
09:53:36 **A.** -- but I don't know.
09:53:37 **Q.** You would defer to an engineer; correct?
09:53:39 **A.** About velocity, yes.
09:53:41 **Q.** About airflow in an operating room; --
09:53:41 **A.** Yes.
09:53:43 **Q.** -- correct?
09:53:44 **A.** Yes.
09:53:44 **Q.** You'd defer to a -- someone that's a --
09:53:48 that's an expert in fluid dynamics; correct?
09:53:53 MR. COREY GORDON: Object to the form of
09:53:53 the question.
09:53:54 **A.** Fluid dynamics to talk about air, you mean?
09:53:57 **Q.** Yes.
09:53:58 **A.** Yeah, I'll talk about the clinical studies,
09:54:00 and they can talk about the basic science of airflow,
09:54:05 absolutely.
09:54:14 **Q.** Are you familiar with Memarzadeh?
09:54:16 **A.** With what?
09:54:17 **Q.** Memarzadeh?

09:54:19 MR. COREY GORDON: Object to the form of
09:54:20 the question.
09:54:20 **Q.** Do you know who he is?
09:54:21 **A.** I don't think so.
09:54:21 **Q.** Okay.
09:54:24 MR. ASSAAD: What was the basis?
09:54:26 MR. COREY GORDON: Memarzadeh? I mean, if
09:54:27 you want to ask him about a specific study or -- I
09:54:31 mean, there are proba --
09:54:31 MR. ASSAAD: Who he is. Who he is.
09:54:31 MR. COREY GORDON: You know, Gabe, I'll bet
09:54:31 --
09:54:33 **Q.** Do you know who Darouiche is? Do you know
09:54:36 who Darouiche is?
09:54:36 MR. COREY GORDON: I'll bet there's several
09:54:38 hundred people in the United States whose last name
09:54:39 is Memarzadeh.
09:54:40 MR. ASSAAD: Okay Corey, great.
09:54:41 **Q.** Do you know who Darouiche is?
09:54:43 **A.** I do.
09:54:43 **Q.** How many Darouiches are there in the United
09:54:46 States, do you think?
09:54:46 **A.** I have no idea.
09:54:47 **Q.** Okay. But you know the Darouiche I'd be
09:54:48 talking about in this case; correct?





09:54:50 **A.** Yes.
09:54:50 **Q.** Okay. You mentioned particles in an earlier
09:55:13 answer. Do you agree that particles can carry
09:55:17 bacteria?
09:55:17 **A.** Yes, some of them can.
09:55:19 **Q.** What do you mean by "some of them"?
09:55:21 **A.** I think the -- I've seen sort of percentages
09:55:24 vary, plus or minus 40 percent or something like that.
09:55:27 **Q.** What percentages carry parti --
09:55:29 In an operating room, what percentage of the
09:55:31 particles carry bacteria?
09:55:32 MR. COREY GORDON: Object to the form of
09:55:33 the question.
09:55:33 **A.** Well I don't know, but I'm giving you what
09:55:35 I've seen printed in the literature, 40 percent.
09:55:39 **Q.** Forty percent of the particles in an
09:55:40 operating room carry bacteria?
09:55:41 MR. COREY GORDON: Object to the form of
09:55:41 the question.
09:55:42 **A.** Forty percent of particles can carry
09:55:46 bacteria. I don't know how well that's been studied
09:55:48 in an operating room by itself, but I'm happy to talk
09:55:50 about particles.
09:55:51 **Q.** Well, so -- Do you have a --
09:55:55 Do you have a citation for that?





09:55:57 **A.** No, I don't.
09:55:58 **Q.** Okay.
09:56:07 (Wenzel Exhibit 4 marked for
09:56:07 identification.)
09:56:07 BY MR. ASSAAD:
09:56:31 **Q.** Exhibit 4 is a copy of your curriculum
09:56:35 vitae. Is this the most up to date copy of your
09:56:37 curriculum vitae?
09:56:38 **A.** I think so.
09:56:42 **Q.** Are you board certified in infectious
09:56:45 disease?
09:56:45 **A.** I'm board certified in infectious disease
09:56:47 and internal medicine.
09:56:48 **Q.** Okay. I don't want to spend too much time,
09:56:52 but please help me out here. I want to go to your
09:56:55 publications --
09:56:56 **A.** Sure.
09:57:03 **Q.** -- which I believe starts on page -- under
09:57:10 your Bibliography. There's no page numbers. I'm
09:57:14 sorry.
09:57:14 **A.** Yeah, there should be. I'm sorry.
09:57:17 **Q.** Well that's what was provided to me.
09:57:19 Is that another mistake?
09:57:20 **A.** Well --
09:57:20 MR. COREY GORDON: Object to the form of





09:57:21 the question.
09:57:21 **A.** -- I don't know if it's a mistake. I wish
09:57:23 they were there to help you.
09:57:24 **Q.** Okay. The bibliography sometimes your name
09:57:28 is first and sometimes it's last or in the middle.
09:57:30 What does that mean with respect to published papers?
09:57:33 **A.** If you're the first author it's you're the
09:57:35 one who really did the work, you were at the front
09:57:38 line doing the work and should get the credit as the
09:57:43 first author. If you're the last author you're
09:57:46 usually the person -- the senior member of the team,
09:57:50 helped design the study and helped perhaps with the
09:57:55 protocol.
09:57:56 **Q.** Okay. And you have text books, and
09:58:01 journal/book section editor, books for general
09:58:04 readership, and monographs. What are the difference
09:58:06 between them?
09:58:07 **A.** Okay. So under the papers, these are --
09:58:12 tend to be peer-reviewed articles published in
09:58:16 journals.
09:58:17 **Q.** Umm-hmm.
09:58:19 **A.** Monographs are sometimes just someone might
09:58:22 say, would you give us a review of something like
09:58:28 surgical-site infections, for example, and you put
09:58:32 together a brief sort of report that's not peer

reviewed. It might be for a meeting, for example.
If you're asking me about the --
What's the other thing you asked about, I guess books or something like that --

**Q.** Yeah.

**A.** -- I wrote? Yeah, I've written -- published already one novel and one non-fiction book, and that's totally separate from the science side.

**Q.** I think I said "textbooks." I think you have eight textbooks here.

**A.** Oh, I'm sorry. Textbooks. What are textbooks?

**Q.** No. I mean, what's the difference between a textbook and a monograph?

**A.** Oh a monograph is usually a very brief sort of summary on a particular topic.

**Q.** Can a monograph be authoritative?

**A.** Less steps than a textbook. Textbooks should be highly referenced in general, so.

**Q.** So the *"Handbook on Hospital Acquired Infections*," you're the author of that; correct?

**A.** That's correct.

**Q.** Published in 1981; correct?

**A.** Yes.

**Q.** You could --





**A.** What pa -- Well let me just -- I'll go try to find.

**Q.** It's under "BIBLIOGRAPHY."

**A.** Yeah. Yeah, go ahead.

**Q.** Are you there?

**A.** Yeah. Thanks.

**Q.** Do you consider that book authoritative?

**A.** Yes.

**Q.** Okay. Do you consider all your writings authoritative?

**A.** Well I'm biased, but of course I think I do.

**Q.** Okay. Were you --
Did you write that whole book or were you just the editor?

**A.** No, I'm the editor. When you see all of these basically I'm the editor, and may have written one or more chapters.

**Q.** But as the editor you -- you review everything in the book?

**A.** Yeah, unfortunately.

**Q.** And you agree with everything that's in the -- in the -- in --

**A.** I don't know if I'd agree with everything, but at the time that the articles came across I thought they were reasonable.





**Q.** What do you mean by "reasonable"?

**A.** That they summed up the literature accurately. If you ask me to go back, for example, to a 1981 publication, do I still believe that? I may not agree with that.

**Q.** Science advances over time; correct?

**A.** No, I'm with you.

**Q.** Otherwise we'd be stuck in the stone age; correct?

**A.** I'm with you.

**Q.** Okay. And -- And even though something might be appropriate at the time, some sort of procedure or medication, later on you might find out that it's -- could be harmful to the patient; correct?

**A.** Sometimes that happens, yes.

**Q.** Okay. I mean, it happens with many products in the world. I mean, we have recalls; correct?
MR. COREY GORDON: Object to the form of the question.

**A.** Yeah, we do have recalls, meaning -- that's where I guess the government, you mean, gets involved, or the FDA.

**Q.** Or it could be a voluntary recall; correct?

**A.** Yes, it could be. That's right.

**Q.** I mean, you expect corporations to be





responsible and not put out harmful products into -- into the market; correct?

**A.** Well I'm an infection control person. I don't want any harmful products.

**Q.** Okay. And in fact, you know, you are an infectious disease person and you would understand that a joint infection is a very serious infection.

**A.** I've seen a number of patients with prosthetic joint infections. Taking care of them, it's a big deal; they suffer physically, emotionally, sometimes financially. They often have miserable follow-up with repeated INDs, incision drainage. They often have a spacer put in, so then -- then they have the prosthesis taken out and put in. So I feel very sorry for those patients, no question.

**Q.** And some of them die.

**A.** Occasionally die.

**Q.** I mean, it's not like an infection, you know, like strep or something that my kid gets.

**A.** Strep can kill you, by the way. I don't want to trivialize --

**Q.** I understand that.

**A.** -- you or your child.

**Q.** But, I mean, much more money is spent on, you know, fixing a joint infection than -- than strep

in the United States.

**A.** Joint infections are somewhere between 50 and $90,000 a case is what it's been estimated at. Strep throat, a lot less.

**Q.** I mean, you agree with me that a joint infection is probably one of the worst infections a person can get in their lifetime.

**A.** Well there are a lot of bad things you can get out there, but it's on my list, and I would pre -- you know, I would put it on your list as a -- if I were consulting with you. I'd say, you don't want this one either. You don't want Ebola, you know, you don't want Zika, you don't want the horrible flesh-eating strep, and you don't want a hip infection after a prosthetic joint.

**Q.** And therefore you would agree that doing everything possible to eliminate joint infections should be done.

MR. COREY GORDON: Object to the form of the question.

**A.** I'm an infection control person. I would love to minimize the risk as much as possible.

**Q.** For example, if you found out that there was a device in the operating room that was contaminating the sterile field, you wouldn't want that device in





the operating room unless it was absolutely necessary; correct?

**A.** Well you're going to get to the Bair Hugger I'm sure with that question, but, I mean, I would want as few organisms around as possible, but I would say as an epidemiologist does that itself link directly to infections, and so I would want to know that.

**Q.** Well safety is paramount; correct?

MR. COREY GORDON: Object to the form of the question.

**A.** Safety -- Safety is very important paramount, sure.

**Q.** I'm not talking about the Bair Hugger, I'm just talking about in general. I mean I hope, as a doctor, if you find out that the device is unsafe and causes harm to a patient, you wouldn't use it; correct?

**A.** Given those statistics I would not want to use it.

**Q.** Okay. And you would agree with me as a doctor that's maybe performing total hip or total knee arthroplasties, that you want to do everything you can to prevent a joint infection because you know how severe a joint infection is.

MR. COREY GORDON: Object to the form of





the question, lacks foundation, as -- assumes facts not in evidence.

**A.** So when you say everything that -- I mean I try to prepare the patients before surgery, that kind of thing?

**Q.** You want to do everything from -- from -- from cleanliness of the operating room, to patient prep, to procedure, technique, to limit the -- the risk of surgical-site infection during a total hip and total knee because of the devastating nature of those types of infections.

**A.** They're definitely devastating, and I would want the systems in the hospital and the personnel in the hospital and the environment to be as clean as possible. I want to lower the rates as much as they can be lowered.

**Q.** I mean, you wouldn't advise keeping a device or instrument in the OR that is contaminated and can increase the risk of a surgical-site infection.

MR. COREY GORDON: Object to the form of the question.

**A.** So, you know, there's nothing sterile, or not much sterile in an operating room. The table itself isn't sterile that you put a patient on. So if you talk about contamination, do I want to go in and





try to irradiate the table, as an example. I'd say, you know, that may be overkill. That table has never been linked to an infection. You know, recently there's some studies that looked at using bioluminescence, for example, and the -- this -- the tray that you put the instruments on, that's not totally sterile. It should be. But if that's not linked to an infection would I want to get rid of the tray, is that what you're saying?

**Q.** Then you need to really listen to my question, sir.

**A.** Okay. I'll try to.

**Q.** Let me read my --

**A.** Yeah.

**Q.** I said -- I said contaminated and increases the risk of infection.

**A.** If you say both, yes.

**Q.** Okay. That's exactly what I said.

**A.** Okay. I was -- I didn't --

**Q.** Let me read the question again.

**A.** Yeah. Go ahead. I didn't hear that first I guess.

**Q.** You wouldn't advise keeping a device or instrument in the OR that is contaminated and can increase the risk of surgical-site infection.

Do you agree with that?
MR. COREY GORDON: I object to the form of the question.
**A.** And shown to increase.
**Q.** Yes.
**A.** Not a rare potential, one in a million, but shown in the -- in the literature to increase infections. If you say it that way, yes.
**Q.** Okay. In the literature?
**A.** If somebody's done a study, in other words.
**Q.** Okay.
**A.** That's what I'm trying to say. Documentation. So you say it's contaminated and linked to infections, I would say, how is it linked to infection, hopefully in some study.
**Q.** But does it have to be in the literature, or can it be just from scientific evidence or common sense?
**A.** Common sense, no. There's a lot of people -- You know, there's a guy by the name of Galileo who defied common sense and found out that, you know, the earth's not the center of the universe. It was common sense before that.
**Q.** Okay. Do you agree it's the responsibility of the corporation that manufactures a medical device





to make sure it's safe?
MR. COREY GORDON: Object to the form of the question.
**A.** Manufacturers do what?
**Q.** A medical device to make sure it's safe?
**A.** I think, yeah, again, I'm interested in infection control, I'm interested in safety. If somebody makes a device, I would hope that they would make it safe.
**Q.** And they're the -- they're responsible for making sure it's safe. Don't you agree?
**A.** I would hope --
MR. COREY GORDON: Same objection.
**A.** -- so, yeah.
**Q.** And in fact, I mean, you've been part of studies, haven't you, where corporations fund studies of their own products to determine whether or not it's clinically effective and safe?
**A.** I've done a number of studies on drugs, for example, used to treat sepsis, and to a one they were all failures.
(Interruption by the reporter.)
(Discussion off the stenographic record.)
**A.** To a single one. To every one of them. I'm





sorry. To a case, if you will, they were all failures.
**Q.** And --
**A.** And we published, by the way.
**Q.** I understand that.
And those studies were funded by the manufacturer of those drugs; correct?
**A.** By the pharmaceutical company, yeah.
**Q.** Okay. Because no one else is going to fund a study regarding their own product.
**A.** Yeah. It's hard sometimes to get NIH to fund private industry.
**Q.** Okay. So usually private industry usually funds their own studies to determine the safety of their -- of their product; correct?
MR. COREY GORDON: Object to the form of the question.
**A.** Well certainly for drugs, which I have a lot of experience with, I -- you know, I haven't really -- I don't think I have any studies that I've done on products.
**Q.** Okay.
**A.** Well urinary catheter apparatus, I have done studies on those.
**Q.** And who funded that study?





**A.** Hmm?
**Q.** Who funded that study?
**A.** It was funded by the industry itself, yeah.
**Q.** Okay. Because industry wants to --
**A.** They --
**Q.** -- perform studies to not --
**A.** Show the safety of their product.
**Q.** You have to let me finish.
**A.** I'm sorry. I'm sorry.
**Q.** The manufacturer wants to fund studies to -- to determine whether or not it's effect -- like clinically effective or a good product, and to determine whether or not it's safe; correct?
**A.** Yes, that's true.
**Q.** Because safety is paramount; correct?
MR. COREY GORDON: Object to the form of the question.
MR. ASSAAD: Basis?
**A.** Safety is a --
MR. COREY GORDON: "Paramount" is a -- is -- presumes everything. Safety is an important consideration, but you can -- you can have a perfectly safe operation that guarantees that there's no surgical-site infections by not doing the surgery.
MR. ASSAAD: I'm asking --

10:10:05 MR. COREY GORDON: There's a balance.
10:10:06 MR. ASSAAD: I'm asking for the legal
10:10:08 basis, not your --
10:10:08 MR. COREY GORDON: The legal balance is
10:10:09 that the word "paramount" is vague.
10:10:12 MR. ASSAAD: Okay. Then say "vague."
10:10:12 MR. COREY GORDON: You were using it in a
10:10:13 particular context and he --
10:10:14 MR. ASSAAD: For the rec --
10:10:15 MR. COREY GORDON: -- he may interpret it
10:10:15 and -- as may the jury, in a different context.
10:10:17 MR. ASSAAD: For the record, I asked for
10:10:18 the objection to my question, and Corey Gordon could
10:10:22 have said just, "vague"; however, he went into a
10:10:25 one-minute discussion on "paramount" and everything
10:10:30 like that.
10:10:30 So going forward, Corey, I request that if
10:10:33 I ask for a basis just tell me the legal basis, not
10:10:35 your reasoning why it's vague, or -- or lack of
10:10:39 foundation. Fair enough?
10:10:40 MR. COREY GORDON: I'm not going to agree
10:10:42 to --
10:10:42 MR. ASSAAD: Okay. So you don't want to
10:10:43 agree to no speaking objections. I understand.
10:10:45 MR. COREY GORDON: I'm not going to agree





10:10:47 to your characterizations.
10:10:48 MR. ASSAAD: Okay.
10:10:49 BY MR. ASSAAD:
10:10:53 **Q.** So with respect to a medical device, you
10:10:58 would agree with me that the responsibility to
10:11:01 determine its safety before it goes on the market is
10:11:04 the manufacturer of the medical device; correct?
10:11:07 **A.** Yeah. That's why they fund studies, to test
10:11:10 both safety and efficacy.
10:11:11 **Q.** And they should fund studies; correct?
10:11:13 **A.** I would hope they would do a lot of funding.
10:11:15 **Q.** Okay. And if -- if there are researchers in
10:11:20 the field that are experts in certain areas and -- and
10:11:23 recommend research to a manufacturer regarding the
10:11:27 safety of their product, they should take that into
10:11:31 consideration in whether or not to do research;
10:11:33 correct?
10:11:34 MR. COREY GORDON: Object to the form of
10:11:35 the question.
10:11:36 **A.** So you're asking if industry makes a
10:11:39 decision as to who does the study; is that what you're
10:11:42 getting at?
10:11:42 **Q.** No. I'm saying that if there is -- if there
10:11:45 is an issue regarding the safety of a product --
10:11:47 **A.** Yeah.





10:11:47 **Q.** -- and the recommendation by, say, for
10:11:50 example, a -- the advisory -- the Scientific Advisory
10:11:56 Board member of -- of a corporation that you need to
10:12:00 do some research regarding the safety of this product,
10:12:03 do you agree that a responsible corporation would
10:12:05 consider doing the research?
10:12:07 **A.** Yeah. If there was a signal somewhere that
10:12:10 the device or a product was unsafe, yeah, they need to
10:12:14 go get some more work to prove it one way or another.
10:12:18 **Q.** You're aware that Dr. Sessler has done a lot
10:12:22 of research regarding maintaining normothermia and the
10:12:27 Bair Hugger.
10:12:27 **A.** Yeah, he has. I don't know everything that
10:12:30 he's done, I have to tell you that.
10:12:32 **Q.** Are you aware that he's on the Advisory
10:12:34 Board for 3M?
10:12:35 **A.** I may have seen that in one of the
10:12:37 depositions. I wasn't aware of that --
10:12:39 **Q.** Are you aware that --
10:12:39 **A.** -- in general.
10:12:40 **Q.** -- he ghost wrote, or not ghost wrote, he --
10:12:44 he -- I'm sorry -- he submitted a study in 2011
10:12:46 regarding particle tests?
10:12:48 **A.** I'm not sure I knew that.
10:12:49 **Q.** Did you not review the 2011 study by -- by





10:12:53 Daniel Sessler and Russ Olmsted?
10:12:57 **A.** I may have, I just can't recall the study.
10:13:00 **Q.** Do you know who Russ Olmsted is?
10:13:02 **A.** No.
10:13:05 **Q.** So going back to your CV under your
10:13:13 bibliography, it seems like you wrote two books,
10:13:20 textbooks in 2014 under "Clinical Decision Support"?
10:13:27 **A.** Oh yeah. That's an online text now, --
10:13:31 **Q.** Do --
10:13:31 **A.** -- resource.
10:13:32 **Q.** Do you consider those authoritative?
10:13:34 **A.** Yeah.
10:13:34 **Q.** Okay.
10:13:35 **A.** I'm biased, but.
10:13:37 **Q.** Okay.
10:13:37 **A.** So you need to know that.
10:13:39 **Q.** Under "Journal/Book Section Editor" you have
10:13:41 seven articles there under -- seven -- seven
10:13:47 journal/book documents.
10:13:49 **A.** Where? Where are we?
10:13:50 **Q.** Right under "Text Books."
10:13:54 **A.** Oh, okay.
10:13:55 **Q.** Do you consider those authoritative?
10:13:58 **A.** If I was involved at the time I did my best
10:14:02 to make those accurate.

10:14:04 **Q.** So you consider those accurate and
10:14:05 authoritative?
10:14:06 **A.** Yeah, at the time that we did it.
10:14:08 **Q.** Okay. What are "Books For General
10:14:10 Readership," are those the two books, your fiction and
10:14:12 nonfiction?
10:14:13 **A.** Yeah. I want you to buy one for everybody
10:14:15 in your corporation so that they can have a good time.
10:14:18 **Q.** Well if you gave me a free copy I may have
10:14:20 been able to recommend it.
10:14:22 (Laughter.)
10:14:22 MR. COREY GORDON: I can recommend it.
10:14:29 **A.** I'll send you a copy later. We'll get you a
10:14:32 co --
10:14:32 MR. COREY GORDON: And I -- I paid for
10:14:33 mine.
10:14:34 THE WITNESS: I'll give you another one.
10:14:36 MS. ZIMMERMAN: If you're reading anything
10:14:39 but literature.
10:14:39 **Q.** Then, under "Monograph," do you consider
10:14:41 those authoritative?
10:14:42 **A.** Yeah, they were -- you know, they were
10:14:45 trying to be up-to-date summaries, they weren't trying
10:14:51 to be in any way in-depth sort of critical reviews.
10:14:55 **Q.** But --





10:14:55 So, for example, under Doebbeling, Herwaldt,
10:14:59 Nettleman, Pfaller and Wenzel, "Hospital-Acquired
10:15:02 Infections: New Challenges," 1991, do you consider
10:15:05 that authoritative?
10:15:07 **A.** It was at the time.
10:15:07 Where are we, though? I just want to make
10:15:09 sure.
10:15:09 **Q.** Under "Monographs," number 2.
10:15:13 **A.** Text Books. Oh, I'm sorry.
10:15:16 Yeah. I mean, I did my best at the time.
10:15:19 **Q.** Who's --
10:15:20 Under "A Guide to Infection Control in the
10:15:23 Hospital," "Editors," that one interested me because
10:15:26 you write: "Over 60,000 copies have been distributed
10:15:28 free of charge --
10:15:29 **A.** Yeah.
10:15:29 **Q.** -- to healthcare workers in the developing
10:15:31 world --
10:15:32 **A.** Yeah.
10:15:33 **Q.** -- countries by the end of 2008."
10:15:34 And by the way, you're missing a space in
10:15:36 your CV between "countries" and "by." You might want
10:15:38 to fix that.
10:15:39 MR. COREY GORDON: And "countries" is
10:15:40 misspelled.





10:15:41 **A.** Oh.
10:15:41 MR. ASSAAD: Yes, and that, too.
10:15:44 MR. GOSS: Mistakes.
10:15:44 **A.** Appreciate that.
10:15:47 **Q.** Was this funded by a nonprofit organization,
10:15:50 or --
10:15:50 **A.** Actually I've been a member of the
10:15:52 International Society for Infectious Disease for a
10:15:56 long time, and was president roughly, I don't
10:15:59 remember, 2008 or '10 or so. And three years before
10:16:03 that I was asked by the former president if I would
10:16:07 organize a handbook; in other words, something that
10:16:09 would fit in a pocket, that would be useful to give to
10:16:16 healthcare workers in countries throughout the world
10:16:18 that are developing countries that really couldn't
10:16:20 afford to buy a text that have no computer resources.
10:16:24 So I did that, and the handbook is just what it looks
10:16:28 like, about a handbook size.
10:16:30 **Q.** And you've updated it periodically, you
10:16:32 started in 1998; correct?
10:16:33 **A.** Yeah.
10:16:34 **Q.** And the last edition was 2008?
10:16:36 **A.** No. That's the last one that I -- and
10:16:38 actually there are -- there are ones I've passed it
10:16:42 over to now, a first editor, Gonzalo Bearman, who's at





10:16:47 our institution, and on the last one, which was
10:16:50 probably 2014 or '15, I was a senior author or senior
10:16:56 editor, if you will. I'm trying to transition to
10:16:59 other people. And so for the next one that'll be out
10:17:01 in a year or two, I won't be editing that.
10:17:06 **Q.** But in any event, you consider that
10:17:08 authoritative.
10:17:08 **A.** Well it's very good for what we're trying to
10:17:11 do.
10:17:12 **Q.** Okay.
10:17:12 **A.** We're trying to provide resources to --
10:17:14 **Q.** Prevent infections.
10:17:16 **A.** Absolutely.
10:17:18 **Q.** So you consider it authoritative and you're
10:17:19 sending it around the world.
10:17:20 **A.** Yeah. No. I mean for -- But it's
10:17:21 targeting, particularly, countries that have limited
10:17:24 resources, so it's not -- it's not an in-depth review,
10:17:28 it's really trying to focus as much as possible on the
10:17:31 problems they face.
10:17:32 **Q.** But you agree with everything in it;
10:17:34 correct?
10:17:36 **A.** Yes, I think so. I've read -- everything
10:17:37 that I have put there I pretty much have reviewed.
10:17:40 **Q.** You're the editor.

10:17:41 **A.** Yeah.
10:17:42 **Q.** Okay. And you're the first-named editor;
10:17:45 correct?
10:17:47 **A.** Most of the time there. With all this,
10:17:48 yeah.
10:17:48 **Q.** I mean you were primari --
10:17:49 **A.** I am now there.
10:17:50 **Q.** But during this time you were primarily
10:17:53 responsible for the book.
10:17:53 **A.** That's correct, yeah.
10:17:54 **Q.** Okay. And I assume that you edited and
10:17:55 reviewed everything that was in -- in here.
10:17:56 **A.** I have, yeah.
10:17:58 **Q.** Okay. And if there's something that you
10:17:59 disagree with it you would have objected to putting it
10:18:02 in there.
10:18:02 **A.** Yeah, or if you find something, I'll take it
10:18:04 look at it.
10:18:05 **Q.** Okay. And do you -- do you consider all
10:18:09 your publications or papers authoritative?
10:18:14 **A.** Well given my bias, which I've told you
10:18:17 before, --
10:18:17 **Q.** Okay.
10:18:18 **A.** -- I'd like to think so.
10:18:20 **Q.** Whether or not you were the advisor or the





10:18:22 first-named author, you consider it authoritative.
10:18:24 **A.** Yeah. I read -- I read the papers that I'm
10:18:26 involved in, yeah.
10:18:28 MR. ASSAAD: Let's take a break for the
10:18:29 court reporter.
10:18:30 THE WITNESS: Okay.
10:18:30 THE REPORTER: Thank you. Off the record.
10:18:33 (Recess taken from 10:18 to 10:31 a.m.)
10:31:02 (Discussion off the stenographic record.)
10:31:02 BY MR. ASSAAD:
10:31:11 **Q.** You mention --
10:31:12 We talked about particles briefly, in -- in
10:31:19 the operating room, and that they can carry bacteria.
10:31:23 Do you agree with me that the reduction of
10:31:32 airborne particles in an operating room is beneficial?
10:31:39 MR. COREY GORDON: Object to the form of
10:31:40 the question.
10:31:43 **A.** So I haven't seen any data to show the
10:31:47 reduction in airborne particles actually reduces
10:31:52 infection rates with maybe, you know, one exception,
10:31:59 the Darouiche study that's more recent where he looked
10:32:03 at particles in bacteria and he modeled particles in
10:32:10 bacteria and said that they correlate, but he actually
10:32:16 didn't show, in a prospective way, that they reduced
10:32:21 infections because he didn't do any microbiology. So





10:32:24 there might be a signal out there, but I'm not aware
10:32:27 of any study that said if I took out Staph -- now
10:32:33 you're just talking about particles maybe, I'm sorry,
10:32:35 maybe I'm mixing this up -- but if I reduce particles
10:32:39 that I would have fewer infection rates. I think
10:32:43 that's what a lot of the laminar flow studies actually
10:32:47 showed didn't occur.
10:32:52 **Q.** So I'm guessing your opinion --
10:32:53 **A.** Yeah.
10:32:54 **Q.** Do you have an opinion whether or not the --
10:33:02 the number of particles over a surgical site have an
10:33:07 effect on surgical-site infections?
10:33:13 **A.** So I guess I would say it this way. If I
10:33:17 knew that there was a hundred percent sort of particle
10:33:21 to bacteria, I'm more interested in bacteria than I am
10:33:25 particles. They're both surrogate markers for what
10:33:30 really is going on. What we really want to know is
10:33:33 what can we do to stop the endpoint, surgical-site
10:33:37 infections. And so then there are some studies that
10:33:39 have tried to say, if I have particles, you know, I
10:33:43 have bacteria. Not all studies have really shown the
10:33:47 same thing always, so there's some discrepancy between
10:33:51 the relationship of particles and bacteria. And
10:33:55 again, the second part of that is if you have bacteria
10:34:00 and -- do they cause the infection.





10:34:03 **Q.** Okay. So my question is again, do you have
10:34:06 an opinion -- do you have an opinion whether or not
10:34:14 the number of particles over a surgical site have an
10:34:18 effect on surgical-site infections; "yes" or "no"?
10:34:21 MR. COREY GORDON: Object to the form of
10:34:22 the question, asked and answered.
10:34:23 **A.** Yeah, I think what I'm trying to do is give
10:34:27 you the best answer I can, you know, --
10:34:28 **Q.** Well --
10:34:29 **A.** -- that, you know, we don't have complete
10:34:32 data yet to really say that particles equal
10:34:37 infections.
10:34:37 **Q.** Okay. So you're not saying that particles
10:34:40 do not equal infections, and you're not saying that
10:34:43 particle -- increased particles increase infections,
10:34:45 you're just saying that there's not enough data.
10:34:47 **A.** Yes.
10:34:48 **Q.** So my understanding is you don't have an
10:34:50 opinion at this point in time whether or not the
10:34:52 number of particles over a surgical site increase the
10:34:55 risks of surgical-site infections.
10:34:57 MR. COREY GORDON: Object to the form of
10:34:57 the question.
10:34:59 **A.** I don't think there are data to say that if
10:35:02 you have a certain number it's going to predict an

infection.

**Q.** So you have no opinion at this time.

**A.** Well that's my opinion.

**Q.** Well your opinion is that there's no data.

**A.** Yeah. We need more data.

**Q.** Okay. So your opinion is you don't have an --

Okay. Do you agree that if you increase the number of particles you increase the risk of surgical-site infection?

MR. COREY GORDON: Object to the form of the question.

**A.** Yeah, I don't think -- I don't think there are data that really show that, so.

**Q.** So you don't agree with that.

**A.** Yeah.

**Q.** So you don't agree with that.

**A.** I don't agree with it.

**Q.** Do you agree that you if you reduce the numbers of particles you decrease the risk of surgical-site infection?

**A.** And again I've cited the studies from the laminar airflow would clearly reduce the number of particles, didn't reduce the number of infections.

**Q.** So you don't agree with that.





**A.** That's right.

**Q.** Okay. So you don't agree that if you reduce the number of particles over the surgical site, you don't reduce -- you don't reduce the --

**A.** Yeah, I think we have firm evidence on that.

(Interruption by the reporter.)

THE REPORTER: So you don't agree that if you reduce the number of particles over the surgical site?

**Q.** -- you reduce the risk of surgical-site infections.

**A.** Yeah. The only signal that I would even point to would be Darouiche.

**Q.** Do you consider Darouiche an expert?

**A.** I think he's done really good work, yeah. So I think he's good.

**Q.** So you consider him an expert?

**A.** Yeah.

**Q.** You do understand that hospitals spend a significant amount of money to reduce the particle load in an operating room.

MR. COREY GORDON: Object to the form of the question.

**A.** Say that again if you would.

**Q.** Hos --





I mean, you understand that there is an HVAC system in the operating room; correct?

**A.** Yes.

**Q.** And it's -- there are -- there are standards in many states regarding the type of filtration to be used in an operating room.

MR. COREY GORDON: Object to the form of the question and lack of foundation.

**A.** I -- I think there are standards.

**Q.** Have you heard of ASHRAE?

**A.** Yes.

**Q.** Okay. And you understand for an operating room, most operating rooms contain two filters?

**A.** Yeah, I think they're MERV 14 or something like that.

**Q.** It's a MERV 7 for the prefilter and the MERV 14 for the final filter. Do you --

Have you heard that before?

**A.** I've heard the 14.

**Q.** Okay. And you understand the purpose of that is to reduce the number of airborne contaminants in the operating room; correct?

**A.** Yes.

**Q.** Okay. And you agree with that; correct?

**A.** I do.





**Q.** Okay. And you understand that in an operating room they control for humidity to limit the amount of bacterial growth.

MR. COREY GORDON: Object to the form of the question.

**A.** Yeah, I don't know the relationship to humidity.

**Q.** Okay. So you're not -- you don't -- you have done no research or have no understanding how humidity affects bacterial growth?

**A.** True.

**Q.** Okay. And you're not an expert in filtration; correct?

**A.** No, only in the sense I don't want to completely -- if you're talking about all filters and nothing to do with infectious diseases, where they interact I think I can make an opinion. But no, I'm not an expert just in filters.

**Q.** You agree that the cleanest air that's coming into the operating room is coming through the vents.

MR. COREY GORDON: Object -- Object to the form of the question, and lack of foundation.

**A.** You mean the filtered air is cleaner than somewhere else?

10:38:38 **Q.** Yes.
10:38:38 **A.** Yeah.
10:38:40 **Q.** Where do you think the greatest bioburden is in the operating room?
10:38:42
10:38:46 **A.** I just saw a bioluminescence study that says the side of the table, I think, in one study. And I'm
10:38:49
10:38:54 not an expert in where the greatest bioburden is, but
10:38:58 so that's the recent study that looked like that.
10:39:00 **Q.** Side of the surgical table?
10:39:02 **A.** And the computer, actually, was very -- was
10:39:05 very high numbers.
10:39:06 **Q.** But the computer is outside of the -- the
10:39:08 sterile field; correct?
10:39:10 **A.** It's --
10:39:10 MR. COREY GORDON: Object to the form of
10:39:11 the question.
10:39:11 **A.** -- outside the sterile field.
10:39:12 **Q.** It's behind the surgeons actually; correct?
10:39:14 **A.** Yeah.
10:39:15 **Q.** Do you agree that there is a significant
10:39:19 amount of bioburden around the surgical table and
10:39:21 underneath the surgical table?
10:39:23 MR. COREY GORDON: Object to the form of
10:39:23 the question.
10:39:24 **A.** So in that one study that I saw with the





10:39:27 bioluminescence is the only data that I know about
10:39:30 burden.
10:39:31 **Q.** Okay. So you only rely on literature and
10:39:33 not on any type of scientific reasoning that you could
10:39:39 draw from that literature?
10:39:40 MR. COREY GORDON: Object to the form of
10:39:41 the question.
10:39:44 **A.** So I'm not sure of the difference. I mean I
10:39:47 would have said the literature -- You read the data,
10:39:50 and then you interpret the data based on maybe a host
10:39:54 of other studies, and together you come up with an
10:39:57 opinion.
10:39:58 **Q.** I understand that. But sometimes you want
10:40:00 to do research and you'll have a hypothesis; correct?
10:40:03 **A.** Yeah. I'm not sure how that relates to the
10:40:05 earlier question.
10:40:07 **Q.** Well I'm saying, like, well you know that
10:40:09 the air coming out of the vents is filtered air;
10:40:11 correct?
10:40:11 **A.** Yes.
10:40:12 **Q.** And you know that there is many people in
10:40:14 the operating room around the surgical table; correct?
10:40:16 **A.** Yeah. Yeah.
10:40:16 **Q.** There is the patient; correct?
10:40:18 **A.** Yeah.





10:40:18 **Q.** There is probably two or three people
10:40:20 performing the surgery in an orthopedic surgery;
10:40:22 correct?
10:40:22 **A.** Yes.
10:40:23 **Q.** And there is an anesthesiologist; correct?
10:40:25 **A.** Yes, there is.
10:40:26 **Q.** And they are shedding skin squames; correct?
10:40:30 **A.** Yeah. People who have studied that said
10:40:32 yeah.
10:40:33 **Q.** Do you disagree with that?
10:40:34 **A.** No.
10:40:35 **Q.** Okay. And therefore, you would agree with
10:40:38 me that the airflow is pushing down the skin squames
10:40:43 to the floor area; correct?
10:40:45 MR. COREY GORDON: Object to the form of
10:40:45 the question, lack of foundation.
10:40:46 **A.** Well I don't know that the airflow is only
10:40:48 pushing things down to the floor. I don't know that.
10:40:50 **Q.** Okay. So sitting here today you don't know
10:40:53 where the greatest bio -- like where the greatest
10:40:56 bioburden is in the operating room, in the air of the
10:40:58 operating room?
10:40:58 **A.** No, --
10:40:58 MR. COREY GORDON: Object to the form of
10:40:59 the question.





10:40:59 **A.** -- the only study is the one I cited.
10:41:02 **Q.** Okay.
10:41:03 **A.** And you know what I'm talking about,
10:41:04 Richard?
10:41:05 **Q.** Yes.
10:41:05 **A.** Yeah.
10:41:07 **Q.** Now you do understand that the surgeons and
10:41:20 the staff in the operating room are trained not to put
10:41:23 their hands below the operating room table.
10:41:26 **A.** I think that's right.
10:41:27 **Q.** Why is that?
10:41:32 **A.** I think that they just try to keep things
10:41:34 right near the field, that's my -- I'm guessing a
10:41:36 little bit on that, but.
10:41:38 **Q.** So as an infectious disease person you don't
10:41:42 understand why they -- they want to keep their hands
10:41:43 -- they're trained to keep their hands always above
10:41:45 the operating room table?
10:41:46 **A.** Well I think they don't want to touch the
10:41:49 side of the table.
10:41:50 **Q.** Yeah, but they're not evened allowed to put
10:41:52 their hands down, and not touch anything.
10:41:54 MR. COREY GORDON: Object to the form of
10:41:55 the question.
10:41:55 **Q.** Do you agree with that?

10:41:59 **A.** Yeah, I don't -- I can't say I've seen rules for that or anything, and you may be right.
10:42:01 **Q.** Okay. So you don't know -- you don't -- you haven't read any literature on -- or strike that.
10:42:05 You haven't looked at procedures or been involved in any training discussing --
10:42:09 **A.** Where they hold their hands.
10:42:12 **Q.** -- or training nurses -- or nurses and surgeons to keep their hands above the operating room table to avoid for their hands to be contaminated.
10:42:13 **A.** I didn't do any research on that, I haven't --
10:42:16 **Q.** Okay.
10:42:19 **A.** -- seen it.
10:42:21 **Q.** By the way, before getting involved in this case did you do -- did you know anything about the Bair Hugger?
10:42:21 **A.** The only thing I knew was the Kurz study was pretty much it.
10:42:22 **Q.** The 1996 *New England Journal of Medicine*?
10:42:23 **A.** That's right.
10:42:26 **Q.** Okay.
10:42:27 **A.** I may have read Melling, but, you know, I just remember the Kurz study.
10:42:29 **Q.** Do you know what the difference between the
10:42:35
10:42:36
10:42:39
10:42:39
10:42:40
10:42:43
10:42:45





10:42:46 Melling study and the Kurz study is?
10:42:48 **A.** I do.
10:42:48 **Q.** What's the difference?
10:42:50 **A.** Well in the Kurz study the authors randomized 200 patients who were undergoing colorectal surgery to warm air with the Bair Hugger, to ambient air, it was double blind study as a result of the -- using the ambient air, and the outcome was surgical-site infections. I'm not sure if you want to know any more about that.
10:42:55
10:42:59
10:43:06
10:43:09
10:43:13
10:43:16
10:43:19 Melling, which was published in 2001, actually took patients who were expected to have a surgical time of about 50 minutes or less --
10:43:24
10:43:29
10:43:33 (Interruption by the reporter.)
10:43:34 THE WITNESS: Fifty, five-oh.
10:43:34 **A.** -- they were clean surgery, there were 421 patients who were randomized. What was different was that they pre-warmed the patients for 30 minutes or more, and... And again, just like the Melling, they showed a 3-to-1 ratio, three times the risk of infection in the warmed patients versus the non-warmed patients. And I want to point out the consistency of that 3-to-1 ratio.
10:43:39
10:43:43
10:43:47
10:43:51
10:43:54
10:43:57
10:44:03
10:44:05 **Q.** Okay. So you do understand that Melling was pre-warming; correct?
10:44:06





10:44:07 **A.** Yes.
10:44:08 **Q.** Okay. It wasn't perioperative warming.
10:44:10 **A.** That's correct.
10:44:11 **Q.** Okay. And I'm sure you're aware of studies that -- recent studies done by Dr. Sessler and others, that forced-air warming has very little effect on core temperature for the first hour when you're warming perioperatively.
10:44:13
10:44:18
10:44:24
10:44:28
10:44:28 MR. COREY GORDON: Object to the form of the question.
10:44:29
10:44:30 **A.** Yeah, I don't -- I don't know that it has no effect or very little effect in the first hour.
10:44:32
10:44:36 **Q.** Well you're aware of those studies; correct?
10:44:38 **A.** I remember hearing --
10:44:38 MR. COREY GORDON: Object to the form of the question.
10:44:39
10:44:39 **A.** -- about but I just can't cite them.
10:44:41 **Q.** Okay. So you're not going to -- I mean --
10:44:45 Well you understand that Kurz was 1996; correct?
10:44:48
10:44:49 **A.** It was 1996.
10:44:50 **Q.** And you understand that Kurz actively cooled patients for the control.
10:44:53
10:44:55 MR. COREY GORDON: Object to the form of the question.
10:44:55





10:44:55 **A.** Kept them at ambient air, yes.
10:44:58 **Q.** Well they didn't keep them am -- They blew ambient air --
10:45:01
10:45:01 **A.** Blew ambient air, --
10:45:01 **Q.** -- which would be
10:45:03 **A.** -- hooked them up ambient air.
10:45:04 **Q.** Which would be a cooling effect on a patient; correct?
10:45:06
10:45:06 **A.** Yes.
10:45:07 **Q.** Okay. That would be unethical today; correct?
10:45:08
10:45:09 **A.** Every -- With the effect of warming, particularly warming a surgical-site infections, nobody should go to the operating room without being warmed.
10:45:11
10:45:14
10:45:16
10:45:17 **Q.** But you would -- you agree you wouldn't be able to do a study and cool patients today.
10:45:18
10:45:21 **A.** No, no. That's what I'm saying.
10:45:21 **Q.** You could be --
10:45:22 **A.** They have to be warm.
10:45:24 **Q.** Okay. And -- And Melling was pre-warming; correct?
10:45:27
10:45:28 **A.** Melling was pre-warming. But there are data to show that the pre-warming actually last up to three hours. I've cited that in my report.
10:45:30
10:45:32

10:45:34 **Q.** Okay. And that's a good thing; correct?
10:45:36 **A.** I think it's a good thing.
10:45:37 **Q.** So you would agree with me that, for example, total hip and total knee arthroplasty, that you could just pre-warm a patient because its effects are for three hours and most of the surgeries last below three hours.
10:45:51 **A.** I don't know anybody --
10:45:51 MR. COREY GORDON: Object to the form of the question.
10:45:56 THE WITNESS: I'm sorry. I didn't mean to interrupt, Corey.
10:45:57 **A.** I don't know anybody who's totally done pre-warming with total hips and knees, if that's what you're asking.
10:46:03 **Q.** You agree with me that there's no study out there that -- that looked at the -- the effects of warming a patient and periprosthetic joint infection.
10:46:12 **A.** That's not quite accurate, because what I've done is show some cohort studies, if you want to refer to those in my report.
10:46:20 **Q.** Can you just give me the name of the study?
10:46:23 **A.** So the --
10:46:24 Well the first was -- I have a chart actually in my report. On the top of the chart it





10:46:29 will say there's a study from Hopkins, there were fi
10:46:34 -- I think I had six -- five or six cohorts. There
10:46:39 was a second study that was done by Leijtens in
10:46:43 Denmark, and that was total hips and total knees.
10:46:48 **Q.** Which is the chart you're referring to?
10:46:52 **A.** Is this my report? Yeah. (Witness
10:46:58 reviewing exhibit.) So page 8. So let's look at --
10:47:04 under number 2, this was by Leijtens, it was done in
10:47:11 Holland, total hips and knees. And what they show --
10:47:14 They -- These people addressed the question, to put it
10:47:17 in perspective, if patients were warmed or -- you
10:47:21 know, during the operation compared to those who
10:47:24 remained hypothermic, was there a difference. And as
10:47:30 you can see, there is a risk ratio of being cool of
10:47:34 3.7. And I would point out again that if you look at
10:47:37 Melling or you look at Kurz, it's about three times
10:47:41 the risk of infections --
10:47:41 **Q.** But the P value --
10:47:43 **A.** -- if you're cool.
10:47:44 **Q.** P value is .061; correct?
10:47:44 (Interruption by the reporter.)
10:47:48 **A.** .061.
10:47:48 THE WITNESS: I'm sorry.
10:47:49 **Q.** And you agree with me that the only
10:47:51 infections were in total hip and not in the total





10:47:53 knee.
10:47:53 **A.** I don't remember. I think that's probably
10:47:54 right, but I don't remember.
10:47:55 **Q.** Okay. And basically there was four out of
10:48:00 109 that were hypothermic, and three out of 306 that
10:48:07 were normothermic; correct?
10:48:08 **A.** Yeah, I don't have it in front of me.
10:48:10 **Q.** Okay.
10:48:10 **A.** But I've said seven -- I have in the chart
10:48:13 27 percent total.
10:48:14 **Q.** Okay. And --
10:48:18 **A.** And nobody, by the way, with that .06 is
10:48:22 going to discard that. If you were having hip surgery
10:48:25 and you were in Holland and you -- and I'm telling you
10:48:27 you have three times the risk plus if you weren't
10:48:30 warmed, are you going to argue with me as a patient
10:48:33 say the P was only .06? I don't think so.
10:48:36 **Q.** You agree with me that all the patients were
10:48:38 warmed with the Bair Hugger in that study.
10:48:40 **A.** They were Bair Hugger.
10:48:40 **Q.** And all of them were warmed; correct?
10:48:43 **A.** Did you say all of them were warmed?
10:48:44 **Q.** I mean they all were warmed with the Bair
10:48:47 Hugger device.
10:48:47 **A.** That was the -- As far as I understand,





10:48:48 yeah.
10:48:49 **Q.** And so basically for a significant number of
10:48:52 them that were warmed with the Bair Hugger, they still
10:48:54 became hypothermic; correct?
10:48:57 **A.** That's correct.
10:48:58 **Q.** Okay. So that might indicate that there
10:49:00 might be something else besides warming a patient that
10:49:03 affects hypothermia.
10:49:05 MR. COREY GORDON: Object to the form of
10:49:06 the question, lack of foundation.
10:49:09 **A.** Say that again to make sure I follow you.
10:49:11 **Q.** Well they were all warmed with the Bair
10:49:12 Hugger; correct?
10:49:13 **A.** They were. They were.
10:49:14 **Q.** And even though you were warmed with the
10:49:15 Bair Hugger, a significant amount of patients, 27
10:49:17 percent, became hypothermic; correct?
10:49:19 **A.** That's correct.
10:49:20 **Q.** Okay. So it is possible that there's
10:49:22 something else besides warming that caused
10:49:27 hypothermia.
10:49:27 MR. COREY GORDON: Object to the form of
10:49:28 the question.
10:49:29 **Q.** That's a bad question.
10:49:30 The patients became hypothermic even though

10:49:33 they were warmed.
10:49:34 **A.** That's easier to answer, yeah. And I have
10:49:36 the -- the 27 percent. That's the figure I reported.
10:49:38 **Q.** So you weren't comparing the use of Bair
10:49:41 Hugger versus the non-use of Bair Hugger with respect
10:49:44 to infection rates in that study; correct?
10:49:46 **A.** Only the endpoint, whether you were warmed
10:49:49 with the Bair Hugger versus not warmed.
10:49:51 **Q.** So you could have been warmed with a -- a
10:49:55 convective blanket in that case; correct?
10:49:59 **A.** They weren't, but if you're asking me as
10:50:01 long as the patient's warmed, do you think they'll do
10:50:03 better?
10:50:04 **Q.** Okay.
10:50:04 **A.** That hasn't been done. I'd love to see a
10:50:07 HotDog versus the Bair Hugger studied.
10:50:09 **Q.** You've never seen that?
10:50:11 **A.** Oh. Never seen a straightforward,
10:50:14 randomized controlled trial of one versus the other,
10:50:16 no.
10:50:17 **Q.** Okay. You've never seen a study that was
10:50:20 authored by -- one of the authors was Andrea Kurz on
10:50:22 that study? That wasn't provided to you by the
10:50:25 defense?
10:50:26 **A.** That was the first study you mean?





10:50:27 **Q.** No. A study with Andrea Kurz and a few --
10:50:29 and Kimberger?
10:50:30 **A.** Tell me about this study.
10:50:32 **Q.** Where they compared the HotDog to the -- the
10:50:35 -- the HotDog to the Bair Hugger to see whether or not
10:50:38 --
10:50:38 **A.** In a prospective clinical trial? I don't
10:50:41 remember that study.
10:50:42 **Q.** Do you only count prospective clinical
10:50:44 trials?
10:50:45 **A.** Well in the hierarchy of quality of
10:50:47 evidence, to me that's number one.
10:50:49 **Q.** Some people disagree with that, though;
10:50:50 correct?
10:50:51 **A.** Some might.
10:50:52 **Q.** Okay. And then we could eliminate number 1,
10:50:55 number 3, and number -- and number 4 because they
10:50:57 didn't deal with total hip and total knee; correct?
10:50:59 **A.** Well I don't think I would --
10:51:00 MR. COREY GORDON: Object to the form of
10:51:01 the question.
10:51:02 **A.** Yeah. I don't think I would eliminate
10:51:03 number 4 either, because I think they were -- they
10:51:06 were orthopedic patients with hip fractures. I don't
10:51:08 think that I would say positively they wou -- that





10:51:11 doesn't have any relevance to --
10:51:13 **Q.** Well let's look at being warmed and not
10:51:16 being warmed, --
10:51:16 **A.** Yeah.
10:51:17 **Q.** -- okay? And that's number 5; correct?
10:51:19 **A.** Yes.
10:51:20 **Q.** Which is the Frisch study; correct?
10:51:21 **A.** Yeah. That's right.
10:51:22 **Q.** And the Frisch study said, hey, it doesn't
10:51:24 matter if you're being warmed because 1 percent got
10:51:27 infections if you were warmed and 1 percent didn't get
10:51:29 it if you weren't warmed; correct?
10:51:30 **A.** So I put that study in to let you know that
10:51:32 --
10:51:32 **Q.** You disagree with it.
10:51:34 **A.** -- I looked at all literature and didn't
10:51:36 just cherry-pick anything.
10:51:38 Now if I want to look at that study, let's
10:51:40 talk about it. Look at the high proportion, for some
10:51:43 reason, that never -- that got cool, 43, thirty -- 44
10:51:48 and 33 percent. And there are a couple other weird
10:51:52 things. The follow-up was six weeks. So really hard
10:51:55 to pick up a lot of deep infections in six weeks.
10:51:58 They didn't regulate the temperature in that study in
10:52:02 the operating room, as you know. And they did





10:52:06 something strange. They said, if you were giving
10:52:10 logical anesthesia they didn't warm the patients
10:52:13 unless the patients became hypothermic.
10:52:17 So a lot of weird things about that study.
10:52:18 But the data, I'm trying to tell you, I didn't try to
10:52:22 hide anything, I put it in there.
10:52:23 **Q.** But we're seeing 44 percent were
10:52:27 hypothermic.
10:52:27 **A.** Yeah.
10:52:28 **Q.** Okay. And -- And -- Of total hip, and 33
10:52:34 percent were hypothermic for total knee; correct?
10:52:39 **A.** That's right.
10:52:39 **Q.** Okay. And you saw no difference in
10:52:41 infection.
10:52:41 **A.** That's correct.
10:52:42 **Q.** Okay. And that was 2017; correct?
10:52:44 **A.** That's right.
10:52:44 **Q.** And out of all the studies dealing with
10:52:47 total hip and total knee that you've listed, that had
10:52:49 the highest number of participants.
10:52:53 **A.** Don't remember the numbers, but maybe.
10:52:56 **Q.** You have it right here under number of
10:52:57 patients.
10:52:57 **A.** Oh, okay. I see what you're saying.
10:52:59 **Q.** You have 600 and --

10:53:00 **A.** Yeah.
10:53:00 **Q.** Okay. You have 2,397; correct?
10:53:03 **A.** Yeah. Of the hips and anything to do with orthopedics, right.
10:53:07 **Q.** And you said a study of only looking at six weeks will not pick up deep joint infections?
10:53:12 **A.** Might miss a lot of them.
10:53:14 **Q.** Okay. Because they may -- they may occur one year after; correct?
10:53:17 **A.** Could be, but at least out three months. I don't know why you wouldn't do that.
10:53:21 **Q.** I mean some of them even occur two years; correct?
10:53:23 **A.** Some people show up two years later. It's always hard to know, you know, did they have an interim -- intermittent bloodstream infection, but out to a year --
10:53:33 (Interruption by the reporter.)
10:53:34 **A.** -- intermittent bloodstream infection that landed on the device.
10:53:37 **Q.** And -- And there are -- there are some case studies out there that indicate that they could have had -- come up and be five years later if there's no intermittent infection. They trace it back to the implant surgery.





10:53:48 **A.** I've heard that there are case reports like that, yeah. I can't cite any.
10:53:52 **Q.** But you've heard of it; right?
10:53:53 **A.** Yeah.
10:53:54 **Q.** And you don't disagree with it.
10:53:55 **A.** If it's a real report, it's a real report, that's what happened.
10:53:58 **Q.** And -- And --
10:53:59 **A.** But what I'm saying is some -- it's really hard as a clinician, facing those patients, was that patient infected at the time of surgery, just so we're clear, or did they went to the dentist, they have horrible teeth, they had a -- you know, some manipulation in the mouth and they got a secondary bacteremia and they settled on the prosthesis. Five years out you can't tell.
10:54:18 **Q.** Well you know that secondary bacterium theory is under a lot of dispute.
10:54:23 **A.** It might be under dispute, but I'm telling you as a clinician standing in front of the patient.
10:54:28 **Q.** Okay. I understand that, but it's not settled whether or not secondary bacterium from the mouth causes a periprosthetic joint infection. You've read articles --
10:54:39 **A.** That's the deba --





10:54:40 There's a debate going on as to whether or not these patients should all be screened by their oral surgeons or not beforehand because it's a worry.
10:55:18 **Q.** Okay. And since you believe that the most likely cause of a surgical-site infection is patient flora, then you would agree with me that the likelihood that the anesthesia machine caused a surgical-site infection is very low.
10:55:41 MR. COREY GORDON: Object to the form of the question.
10:55:44 **A.** In general I think that's true.
10:55:47 **Q.** Okay.
10:55:48 **A.** Would there be an exception, an outbreak or something like that where something happened? Yeah. But that's what I would say in general, yes, I think it's low.
10:55:54 **Q.** We're talking probabilities here.
10:55:55 **A.** Yeah. No, I'm with you.
10:55:57 **Q.** And you agree with me that the probability that a surgical light causes a surgical-site infection is very low.
10:56:05 (Interruption by the reporter.)
10:56:05 **A.** Yeah, I don't think I've seen any studies related to that.
10:56:08 **Q.** And you'd agree with me that comput -- the





10:56:11 likelihood that computer monitors cause a surgical-site infection, or the fans in them cause a surgical-site infection is very low.
10:56:18 **A.** Yeah. I haven't seen any data linking them.
10:56:23 **Q.** Okay. And you agree with me that the computer console and the equipment in them, the likelihood of them causing a surgical-site infection is very low.
10:56:33 **A.** And again I can't cite any papers that link them, yeah.
10:56:36 **Q.** So you agree with me.
10:56:37 **A.** Yeah.
10:56:37 **Q.** Okay. You agree with me that the electrocautery device itself has a very low likelihood of causing a surgical-site infection.
10:56:52 **A.** Based on not having any data, yeah.
10:56:54 **Q.** So you agree with me.
10:56:55 You agree with me that a bovie is very unlikely to cause a surgical-site infection.
10:57:03 MR. COREY GORDON: Object to the form of the question, also I guess that's asked and answered.
10:57:07 **A.** I just -- Yeah, I just don't know any data with the bovie or the knife or...
10:57:19 **Q.** You agree with me that sterile surgical drapes are very unlikely to cause a surgical-site

10:57:39 infection.
10:57:40 MR. COREY GORDON: Object to the form of
10:57:42 the question.
10:57:42 **A.** I would say that anything sterile is
10:57:45 unlikely to cause an infection.
10:58:23 **Q.** You agree with me that the cabinets along
10:58:26 the walls are very unlikely to cause a surgical-site
10:58:30 infection.
10:58:31 **A.** Same answer. I haven't seen any data. I
10:58:34 think it's unlikely.
10:58:35 **Q.** You agree with me that the suction drain
10:58:38 that's in the operating room is very unlikely to cause
10:58:40 a surgical-site infection.
10:58:42 **A.** Yeah, I think drains have been known to
10:58:44 harbor certain organisms like Pseudomonas, but again,
10:58:48 if you say standard procedures that have been, you
10:58:53 know, done to try to minimize that, I think it's
10:58:55 unlikely.
10:58:56 **Q.** And when I ask you these questions, doctor,
10:58:58 let's just assume that the hospital, the doctors and
10:59:01 the nurses are following the standard of care.
10:59:02 **A.** I'm with you.
10:59:02 **Q.** Okay.
10:59:05 **A.** I'll follow that.
10:59:05 **Q.** Okay. Like, for example --





10:59:05 **A.** I like infection control, so I'm with you.
10:59:07 I'll imagine the perfect hospital.
10:59:09 **Q.** Okay. Like, for example, we're not
10:59:10 expecting a nurse to take off her mask and sneeze
10:59:13 right into the surgical site, you know, okay?
10:59:16 **A.** I would hope so.
10:59:17 **Q.** Okay. You agree with me that sterilized
10:59:25 surgical instruments are very unlikely to cause a
10:59:27 surgical-site infection.
10:59:28 MR. COREY GORDON: Object to the form of
10:59:29 the question.
10:59:29 **A.** Yeah, in general again, anything sterile.
10:59:32 Now once they're used they're no longer sterile, but,
10:59:36 yes, I think that's true, and I agree with you.
10:59:39 **Q.** Yeah, I understand that when you cut the
10:59:41 skin they may no longer be sterile; correct?
10:59:43 **A.** Yes. That's correct.
10:59:44 **Q.** However, you do understand that in
10:59:45 orthopedic implant surgeries the standard of care is
10:59:48 after you make the first incision -- or some surgeons
10:59:50 would say after you make the first incision to switch
10:59:53 the scalpel.
10:59:54 **A.** Yes.
10:59:54 MR. COREY GORDON: Object to the form of
10:59:55 the question, lack of foundation, assumes facts not





10:59:59 in evidence.
11:00:00 THE WITNESS: Sorry.
11:00:07 **Q.** The drop buckets for a used sponge, do you
11:00:10 agree with me that they're very unlikely to cause a
11:00:13 surgical-site infection?
11:00:14 **A.** Again I'll say the same thing, you know, I
11:00:16 don't know any data, so I think it's low probability.
11:00:32 **Q.** And same question with the trash receptacle.
11:00:35 You agree with me the trash receptacle is very
11:00:37 unlikely to cause a surgical-site infection.
11:00:39 **A.** Yes.
11:00:41 **Q.** And do you agree with me that surgeons
11:00:45 moving their hands is very unlikely to cause a
11:00:50 surgical-site infection?
11:00:51 MR. COREY GORDON: Object to the form of
11:00:53 the question.
11:00:54 **A.** So a surgeon doing surgery is moving his
11:00:57 hands.
11:00:57 **Q.** He's moving his hands like this
11:00:59 [demonstrating].
11:00:59 **A.** Yeah. And is that a cause, assuming that
11:01:04 nothing else is happening? Yeah, I don't think the
11:01:06 movement of hands. Now people talk about the movement
11:01:09 of hands creating more particles and whether that's
11:01:14 linked, we talked about that earlier. It's hard to





11:01:16 show a link with particles and surgical-site
11:01:19 infections.
11:01:56 **Q.** Have you read Dr. Mont's expert report?
11:01:59 **A.** Yes, I did look at that.
11:02:00 **Q.** Okay.
11:02:01 **A.** Yeah.
11:02:01 **Q.** Do you criticize anything in his report?
11:02:04 **A.** Yeah, I don't think I saw anything that I'd
11:02:06 criticize.
11:02:06 **Q.** Okay. Do you believe that -- Have you read
11:02:06 --
11:02:37 Have you read all the defense expert
11:02:38 reports, all the -- all 12 others?
11:02:41 **A.** No, I don't think I read 12.
11:02:43 **Q.** Okay. Have you read Dr. Ho's expert report?
11:02:47 **A.** No, I didn't see that.
11:02:49 **Q.** Have you read Dr. Kuehn's expert report?
11:02:51 **A.** No.
11:02:51 **Q.** Have you read Dr. Abraham's expert report?
11:02:57 **A.** No.
11:03:00 **Q.** So what expert reports have you read? Dr.
11:03:04 Borak?
11:03:04 **A.** Borak, Holford.
11:03:08 On this side of the table you mean?
11:03:09 **Q.** Yes.

11:03:11 **A.** Mont. I'm not sure who else. I think that
11:03:18 -- that may be it, I don't remember.
11:03:20 **Q.** Have you met Dr. Mont?
11:03:22 **A.** Just at Science Day is the only time.
11:03:24 **Q.** Have you met anyone from 3M in preparation
11:03:25 of your expert report?
11:03:27 **A.** No.
11:03:28 **Q.** Have you not met Al Van Duren?
11:03:30 **A.** No.
11:03:30 **Q.** Have you read Al Van Duren's deposition?
11:03:32 **A.** No.
11:03:33 **Q.** You haven't read his 30(b)(6) deposition?
11:03:36 **A.** No.
11:03:36 **Q.** Do you know what a 30(b)(6) --
11:03:36 **A.** No, --
11:03:37 **Q.** -- deposition is?
11:03:38 **A.** -- have no idea.
11:03:39 **Q.** So have you --
11:03:41 Have you read Gary Hansen's deposition?
11:03:44 **A.** No.
11:03:44 **Q.** Have you read any other --
11:03:45 Have you read any other depositions besides
11:03:47 expert depositions?
11:03:48 **A.** No, I don't think so.
11:03:49 **Q.** Well that's not exactly true, --





11:03:49 MR. COREY GORDON: Yeah.
11:03:51 **Q.** -- and I apologize for that.
11:03:52 MR. COREY GORDON: Kurz and Sessler.
11:03:53 **A.** Oh, I'm sorry.
11:03:55 **Q.** You've read the depositions listed in
11:03:56 Exhibit --
11:03:56 **A.** Yeah. I'm sorry. I didn't -- I thought you
11:03:58 meant from 3M or something.
11:04:00 **Q.** Exhibit, I think it's 3?
11:04:03 MR. COREY GORDON: 2.
11:04:06 **Q.** 2.
11:04:06 So besides these depositions listed in
11:04:08 Exhibit 2, what other depositions -- Strike that.
11:04:11 You've read Holford, Borak and Mont. Any
11:04:14 other depositions you reviewed that are on the defense
11:04:17 side?
11:04:20 **A.** I don't -- I don't think so. I don't recall
11:04:22 any other ones.
11:04:38 **Q.** You actually -- Before I get there.
11:04:40 And you've read the depositions of
11:04:46 plaintiffs' experts; correct?
11:04:48 **A.** I read Jarvis, Samet, and I think I've read
11:04:57 Augustine.
11:04:58 **Q.** You think Augustine is on the plaintiffs'
11:05:00 side?





11:05:00 **A.** Oh, I'm sorry. I don't --
11:05:03 Do I think he's on the plaintiffs' side? I
11:05:07 thought so.
11:05:08 **Q.** Why did you think that? Did someone tell
11:05:13 you that?
11:05:14 **A.** No. I mean, he -- he is in charge of the
11:05:16 company making the competitor.
11:05:19 **Q.** Well there's a lot of competitors, aren't
11:05:21 there?
11:05:21 **A.** Well I think that's the key one we're
11:05:23 focusing on if we're really going to be talking man to
11:05:26 man here. That's the one that's --
11:05:27 **Q.** Let's talk man to man.
11:05:29 **A.** Yeah.
11:05:29 **Q.** Let's talk man to man.
11:05:31 (Laughter.)
11:05:32 MS. ZIMMERMAN: I'm going to excuse myself
11:05:33 for this.
11:05:34 (Laughter.)
11:05:34 THE WITNESS: I'm sorry. I meant that as
11:05:36 kind of a joke.
11:05:38 **Q.** So, I mean, have you heard of VitaHEAT?
11:05:40 **A.** No, I don't --
11:05:40 **Q.** VitaHEAT was a competitor of 3M that 3M just
11:05:43 bought. Are you aware of that?





11:05:45 **A.** No, I didn't.
11:05:45 MR. COREY GORDON: Object to the form of
11:05:46 the question, assumes facts not in evidence.
11:05:46 THE WITNESS: Sorry.
11:05:48 **Q.** Are you aware of Mistral?
11:05:49 **A.** No.
11:05:49 **Q.** Are you aware of WarmTouch?
11:05:51 **A.** I've heard of WarmTouch, yeah.
11:05:51 **Q.** Okay.
11:05:52 **A.** I think WarmTouch is what they use at
11:05:54 Hopkins.
11:05:55 **Q.** Okay. So there's other forced-air warming
11:05:57 devices as well as convective devices; --
11:05:57 **A.** Yeah.
11:05:59 **Q.** -- correct?
11:06:00 **A.** Yeah.
11:06:01 **Q.** Okay. And you're aware that, you know,
11:06:05 other competitors of 3M have done research to compare
11:06:09 their product to the Bair Hugger.
11:06:14 **A.** I don't -- I mean, the only ones I've seen
11:06:16 have really been the HotDog and, you know, and, let's
11:06:23 say, Augustine's new study which I don't know if it's
11:06:27 --
11:06:27 **Q.** I don't want to talk about that today.
11:06:28 **A.** -- it's on the table or not, but yeah.

11:06:34 **Q.** I mean, there's -- there's Warm --
11:06:37 **A.** And the McGovern study I mean obviously is the big study you have for your side of the table.
11:06:43 **Q.** Well is that what someone told you?
11:06:43 **A.** Not --
Are you asking me if someone told me that?
11:06:47 **Q.** I mean -- I mean, you say you thought --
11:06:49 **A.** Why do I say that?
11:06:50 **Q.** -- you thought Augustine was on the plaintiffs' side. Why would you make that assumption?
11:06:52 **A.** Because he compared, you know, his product to the Bair Hugger in the new study --
11:06:56 **Q.** You're aware that --
11:07:00 **A.** -- which you don't want to talk about, but.
11:07:03 **Q.** You're aware that Augustine invented the Bair Hugger; correct?
11:07:05 **A.** I do, yeah.
11:07:07 **Q.** Okay. So do you criticize any of his older studies that he did on Bair Hugger before he left Arizant?
11:07:08 **A.** I don't know if I know all of his old studies, but I think -- you know my opinion. I think the Bair Hugger works, I think there are no data out there to definitively link it to harm.
11:07:15 **Q.** Well we have two studies that you just





11:07:15 indicated that you -- that it support your opinion
11:07:17 that Bair Hugger works for total hip and total knee.
11:07:20 One said it doesn't make a difference, --
11:07:24 **A.** Umm-hmm.
11:07:28 **Q.** -- and the other was where they compared
11:07:29 Bair Hugger -- and one where the Bair Hugger was used
11:07:32 all the time and indicated even when you used the Bair
11:07:36 Hugger that it didn't maintain hypothermia; correct?
11:07:38 MR. COREY GORDON: Object to the form of
11:07:39 the question, mischaracterizes his testimony, --
11:07:42 **Q.** Isn't that what those studies say?
11:07:45 MR. COREY GORDON: Let me finish my
11:07:48 objection, please.
11:07:52 MR. ASSAAD: Okay.
11:07:53 MR. COREY GORDON: -- misstates the
11:07:54 evidence, form.
11:07:56 **Q.** We can go back if you want, doctor.
11:07:58 Do you want to go back? Let's go back.
11:07:58 **A.** Let's do that. That'd be fine.
11:07:59 **Q.** Let's be 100 percent correct what these
11:07:59 studies say.
11:08:00 **A.** Yeah, that's fine.
11:08:02 **Q.** Because we want to be accurate; correct?
11:08:04 **A.** Yes.
11:08:05 **Q.** We don't want to be an advocate for the





11:08:08 defense. You want to be --
11:08:08 **A.** I'm not an advocate.
11:08:13 **Q.** You want to be objective; correct?
11:08:15 **A.** Yes. That's --
11:08:16 **Q.** Okay.
11:08:16 **A.** That's good.
11:08:16 **Q.** Being objective is really important when
11:08:17 thousands of people's -- of lives are at stake;
11:08:18 correct?
11:08:21 **A.** Yes.
11:08:21 **Q.** Okay. And what page are you looking at,
11:08:22 sir?
11:08:25 **A.** Page 8.
11:08:26 **Q.** Okay. So let's look at the two studies that
11:08:27 dealt with total hip and total knee.
11:08:29 **A.** Yep.
11:08:31 **Q.** Okay. One was the one in Holland; correct?
11:08:32 **A.** Yes.
11:08:34 **Q.** Where Bair Hugger was used on all the
11:08:35 patients; correct?
11:08:36 **A.** Yes. That's my understanding.
11:08:37 **Q.** And even when the Bair Hugger is used, 27
11:08:38 percent of the people still became hypothermic;
11:08:41 correct?
11:08:43 **A.** That's correct.





11:08:44 **Q.** That would indicate that the Bair Hugger may
11:08:48 not maintain normothermia during a surgery; correct?
11:08:51 **A.** For that study that's correct.
11:08:52 **Q.** Okay. And that looks --
11:08:54 And that showed a 3.7 percent if they were
11:08:58 --
11:08:58 **A.** No, not "percent." It's a risk ratio.
11:09:00 **Q.** You have percent there, sir.
11:09:01 **A.** Oh, I'm sorry. It's both.
11:09:03 **Q.** Okay. And one per -- if they're
11:09:06 hypothermic; correct?
11:09:06 **A.** Yes.
11:09:07 **Q.** So there might be something else in the oper
11:09:10 --
11:09:10 MR. COREY GORDON: I think you misstated
11:09:12 that.
11:09:13 MR. ASSAAD: I don't think I misstated it.
11:09:15 MR. COREY GORDON: You said one percent if
11:09:17 they're hypothermic.
11:09:17 MR. ASSAAD: I said -- I thought I said
11:09:19 "warmed." Did I say --
11:09:19 **A.** One percent if warmed, versus 3.7 if
11:09:22 hypothermic.
11:09:23 **Q.** Okay. And the p value was -- would indicate
11:09:26 to many people out in the research field that it's not

statistically significant; correct?
MR. COREY GORDON: Object to the form of the question.
**A.** I think many people who are out there would not blow this off at .06.
**Q.** They would do further studies, wouldn't they?
**A.** Well they probably would do further studies, yes. But I think no one would discount that is what I've told you earlier if I were advising a patient and that's all we had.
**Q.** Okay. But we could agree with this study on number 2, the Holland study on Exhibit 1, page 8, that the Bair Hugger, even when used, still may not maintain normothermia; correct?
**A.** That's true.
**Q.** Okay. And then let's look at the study that indicate that when the Bair Hugger is used and not used; correct? And we see that when the Bair Hugger is used --
**A.** Which study are you on?
**Q.** Number 5, the Frisch study.
**A.** Okay. Yeah.
**Q.** Okay.
-- there is a 1 percent infection rate;





correct?
**A.** Yes.
**Q.** And when the Bair Hugger is not used there is a 1 percent infection rate; correct?
**A.** Yes.
**Q.** Okay. So the Frisch study indicates that -- the Frisch study actually tested the infection rates when the Bair Hugger is used as compared to when the Bair Hugger is not used; correct?
**A.** Used versus not used?
**Q.** Yeah.
**A.** Well they looked at who got cool with the Bair Hugger versus who didn't get cool with the Bair Hugger.
**Q.** You mean warm.
**A.** Huh?
**Q.** You mean warm.
**A.** Warmed. I'm sorry.
**Q.** We're not cooling with Bair Huggers; are we?
**A.** We're what?
**Q.** We're not cooling with Bair Huggers.
**A.** No, no. I'm sorry.
**Q.** Okay. That would be unethical; correct?
**A.** No, but the percent --
What I'm saying is, you know, they had the





percent here who were under 36 degrees, no question, in a high proportion, unusually high proportion. A lot of strange things which I've already documented about this study. But that's what they showed; no difference, one percent at face value.
**Q.** And every -- every study has limitations; correct?
**A.** Every study can be looked at carefully.
**Q.** Okay. And if you're an advocate you're going to discredit the studies and look at their limitations, and if you're an advocate for a side you're going to not look at the limitations.
**A.** Well --
MR. COREY GORDON: Object to the form of the question.
**A.** -- I don't think that's true.
**Q.** Okay.
(Interruption by the reporter.)
(Discussion off the stenographic record.)
BY MR. ASSAAD:
**Q.** So going back to what depositions you've read, you've been working on this case for -- since 2015; correct?
**A.** I think that's right.
**Q.** Okay. So over -- almost --





**A.** Two years.
**Q.** -- two, two and a half years; correct?
And you actually have seen internal documents from 3M; isn't that true?
**A.** I don't know what documents you're talking about.
**Q.** I mean, you've read depositions in the Walton case.
**A.** Oh, I have seen those. Is that what you mean by that?
**Q.** Yes.
**A.** In the Walton case, yeah.
**Q.** And you --
And you've read depositions and you've had internal documents provided to you in the Walton case.
**A.** Yeah, I haven't looked at Walton for, you know, almost the two years so I can't remember all the things I looked at or not, but I had certainly read everything that I could get my hands on and that they sent.
**Q.** Okay. And were you told not to include any of the -- any internal documents --
**A.** No.
**Q.** -- in -- in your report?
**A.** No.

11:13:14 **Q.** Okay. When'd you start writing your report?
11:13:38 **A.** I tend to not wait till the last second, so I probably started, I'm going to estimate, even a year ago, you know, just to fill out the general areas, you know, what data were available from clinical trials, pretty much trying to look at the hierarchy of the clinical quality, so then I had cohorts, case-control studies and if I learned anything more, and then eventually increased the size of the tables if I was making a table.
11:14:16 **Q.** So you're telling me the report that you wrote in Walton --
11:14:19 **A.** Oh, Walton, way back when.
11:14:22 **Q.** Did you not use any of that report in this report?
11:14:25 **A.** Yeah, there probably were some same things in terms of the background, some of the same studies, but I think I kept finding more and more studies is all I'm saying, in more recent time.
11:14:39 **Q.** I understand that, but you started working on this report probably during Walton; correct?
11:14:43 **A.** Yeah. That's fair.
11:14:44 **Q.** Okay.
11:14:44 **A.** I mean I did a report for Walton, and then, you know, when I was asked to make comments there was





11:14:51 only one patient.
11:14:53 **Q.** And this was on May 29th, 2015.
11:14:55 **A.** It was way back.
11:14:56 **Q.** Okay. And you didn't start all over in this case; did you?
11:15:02 **A.** No. I had the basic -- a basic report for Walton, that's true.
11:15:06 **Q.** Okay. All right. And so you've been working on this report since early of 2015.
11:15:13 **A.** Yeah, you could say that.
11:15:15 **Q.** I mean, your Walton report is -- is approximately 40 pages; --
11:15:24 **A.** Umm-hmm.
11:15:24 **Q.** -- correct?
11:15:25 Does that sound about right?
11:15:26 **A.** I don't remember, but that's about right, yeah.
11:15:28 **Q.** Okay. Have you compared your Walton report to -- to your current report which is Exhibit 1?
11:15:34 **A.** I -- I haven't gone back and tried to look line by line or area by area. My guess, it comports to similar things.
11:15:53 MR. ASSAAD: I only have one copy of this, but let's mark this as Exhibit Number?
11:16:01 THE REPORTER: Five.





11:16:01 (Discussion off the stenographic record.)
11:16:01 (Wenzel Exhibit 5 marked for identification.)
11:16:31 (Discussion off the stenographic record.)
11:16:36 BY MR. ASSAAD:
11:16:37 **Q.** I represent to you that Exhibit Number 5 is a copy of part of your Walton report that indicates the materials that you reviewed in preparation of the Walton report. Does that look familiar?
11:16:52 MR. COREY GORDON: Object to the form of the question, mischaracterizes the document.
11:16:55 **A.** I don't remember this at all, no.
11:16:58 **Q.** Can I see that document real quick, because I only have one copy?
11:17:01 **A.** Yeah, sure. (Handing.)
11:17:02 **Q.** Do you recall reading the depositions of any of those individuals during the Walton case?
11:17:13 **A.** I actually don't remember any of that, no. Can't recall.
11:17:16 **Q.** Can I have it again, sir?
11:17:16 **A.** (Handing.)
11:17:21 **Q.** Did you look at medical records in the Walton case?
11:17:23 **A.** I did.
11:17:24 **Q.** Okay. Did you ever look at the operating





11:17:31 manual for the Bair Hugger Model 750?
11:17:34 **A.** I think I looked at that some time ago. I don't remember much about it, but.
11:17:40 **Q.** It's not listed in Exhibit 1 anywhere.
11:17:42 **A.** Yeah.
11:17:42 **Q.** Or in the documents that you considered.
11:17:45 **A.** I may have looked at that with the Walton case or something way back when, but I just don't remember.
11:17:51 **Q.** Do you remember receiving many internal documents, as indicated here in Exhibit 5, from 3M?
11:17:57 **A.** I just can't recall that, so I don't know. Yeah.
11:18:00 **Q.** Well what's been provided today, --
11:18:01 **A.** Yeah.
11:18:04 **Q.** -- are those all the documents that were provided to you by any of the attorneys for 3M, from Blackwell Burke or from Greenberg Traurig?
11:18:08 MR. COREY GORDON: Object to the form of the question.
11:18:12 **A.** I think I was focusing on sort of this general type of causation question. Was there anything from Blackwell? I don't know.
11:18:22 **Q.** Did you re --
11:18:25 So you're sitting here today, you didn't

11:18:27 rely on any of the documents, internal documents from
11:18:30 3M.
11:18:31 **A.** No. I mean I told you what I have, and...
11:18:34 **Q.** Okay. Well this is what you have for the
11:18:43 multidistrict litigation; correct?
11:18:45 **A.** Yes.
11:18:45 **Q.** Do you have another file or box of documents
11:18:47 that you had for Walton?
11:18:51 **A.** I don't have anything that I remember a
11:18:53 separate file. I mean, my office looks like a mess
11:18:55 right now, but --
11:18:56 **Q.** You do understand the Walton case is still
11:18:58 going on.
11:18:59 **A.** I don't know anything about where it is.
11:19:02 **Q.** Okay. So have you destroyed them?
11:19:04 **A.** No.
11:19:05 **Q.** Okay. So you believe you still have them,
11:19:07 you just don't know where they are.
11:19:08 **A.** Yeah.
11:19:09 **Q.** Okay. So my understanding is that the
11:19:58 expert report of Nurse Hughes was never provided to
11:20:01 you; correct?
11:20:02 **A.** That's true.
11:20:04 **Q.** And did you review the expert report of Dr.
11:20:10 Mont?





11:20:11 MR. COREY GORDON: Objection, asked and
11:20:12 answered.
11:20:14 MR. ASSAAD: I asked him about the
11:20:15 deposition.
11:20:15 MR. COREY GORDON: The deposition?
11:20:16 MR. ASSAAD: Yeah. I'm asking about the
11:20:18 report this time.
11:20:18 MR. COREY GORDON: You mean the transcript
11:20:19 that didn't exist until about an hour ago?
11:20:21 MR. ASSAAD: The expert report.
11:20:23 MR. COREY GORDON: That was -- That was
11:20:24 asked and answered.
11:20:26 MR. ASSAAD: Well let me ask it again,
11:20:27 because I don't -- I was going through this list and
11:20:29 it's not on this list.
11:20:30 MR. COREY GORDON: That's fine.
11:20:31 MR. ASSAAD: It's not worth fighting about.
11:20:33 MR. COREY GORDON: No, it isn't.
11:20:34 **A.** No. I remember most reading -- most
11:20:36 recently reading the -- I guess it's the deposition.
11:20:40 **Q.** So you've never seen the expert report of
11:20:42 Dr. Mont.
11:20:42 **A.** I think... I'm not sure, okay?
11:20:45 **Q.** Well if it's not listed in your --
11:20:47 **A.** Yeah.





11:20:47 **Q.** -- in Exhibit 2, --
11:20:48 **A.** Yeah.
11:20:49 **Q.** -- then you most likely didn't receive it.
11:20:50 **A.** Yeah, I don't -- I don't recall it, that's
11:20:52 all.
11:20:52 **Q.** You didn't receive the expert report of Dr.
11:20:54 Keen; correct?
11:20:55 **A.** That's true.
11:20:55 **Q.** You did not receive the expert report of Dr.
11:20:59 Kuehn; correct?
11:21:00 **A.** Correct.
11:21:01 **Q.** Or Kuehn [keen]. I say Kuehn [coon] just to
11:21:01 distinguish between the two.
11:21:01 **A.** Okay. Yeah.
11:21:02 **Q.** You didn't receive the expert report of Dr.
11:21:04 Settles; correct?
11:21:05 **A.** Yes. True.
11:21:06 **Q.** You did not receive the expert report of Dr.
11:21:08 Abraham; correct?
11:21:08 **A.** That's true.
11:21:10 **Q.** Okay. Did you see any of the vid --
11:21:15 You said you saw the videos of what Abraham
11:21:18 prepared at Science Day; correct?
11:21:20 **A.** Yeah.
11:21:21 **Q.** Did you ever review those again?





11:21:22 **A.** No.
11:21:22 **Q.** Did you ever go online to review them?
11:21:24 **A.** No.
11:21:25 **Q.** Have you ever been to any of the websites
11:21:26 prepared by Blackwell Burke to -- to do a -- a
11:21:31 marketing campaign of the benefits of forced-air
11:21:34 warming?
11:21:35 MR. COREY GORDON: Object to the form of
11:21:36 the question.
11:21:37 **A.** I don't remember doing that, no.
11:21:39 **Q.** Are you aware that Blackwell Burke is trying
11:21:40 to influence the jury in Minnesota?
11:21:42 MR. COREY GORDON: Object to the form of
11:21:43 the question, move to strike.
11:21:45 **A.** I'm not aware of that.
11:21:46 **Q.** Okay. Are you aware of any law firm that's
11:21:48 representing a manufacturer of a medical device that
11:21:53 actually puts out a website and promotes the -- and
11:21:55 markets the medical device on their own -- on the
11:21:58 website?
11:21:58 MR. COREY GORDON: Object to the form of
11:22:00 the question, lack of foundation.
11:22:01 **A.** So --
11:22:01 **Q.** Are you aware of that, "yes" or "no"?
11:22:02 **A.** So say it again. Just want to make sure I

understand.
**Q.** Are you aware of a law firm that actually markets a medical device for a company?
**A.** No, I'm not.
**Q.** Okay. You're not a -- You're not familiar with how particles move in airflow; are you?
**A.** No.
**Q.** Okay. Have you been provided the expert report of Dr. Lampotang?
**A.** No.
**Q.** Do you know who Dr. Lampotang is?
**A.** No, I don't.
**Q.** Well do you know who Dr. Mont is?
**A.** Dr. Mont, yes.
**Q.** Okay.
**A.** I met him at --
**Q.** Science Day.
**A.** -- Science Day.
**Q.** Are you --
Do you know any of the experts, like besides Science Day in this -- in this case?
**A.** You mean like Holford?
**Q.** Yes.
**A.** Just met him once.
**Q.** When?





**A.** There was a meeting in Washington that counsel was there and Jonathan -- blanking on his last name now.
**Q.** Borak?
**A.** -- Borak was there, yeah.
**Q.** So it was you --
**A.** That's the first time that we met for a couple hours in Washington.
**Q.** It was you, Dr. Borak and Dr. Holford?
**A.** Yeah.
**Q.** Any other experts?
**A.** No.
**Q.** Was that the first time you met Dr. Borak?
**A.** It was.
**Q.** Was it the first time you met Dr. Holford?
**A.** It was.
**Q.** Do you know Dr. Hannenberg?
**A.** What's the name?
**Q.** Do you know Dr. Hannenberg?
**A.** No, I don't.
**Q.** Have you looked at the expert report of Dr. Hannenberg?
**A.** No.
**Q.** What about Dr. Ho?
**A.** No.





**Q.** You haven't seen his expert report; correct?
**A.** I have not.
**Q.** And what about Ulatowski; have you seen his expert report?
**A.** Who?
**Q.** Ulatowski?
**A.** No.
**Q.** At the time of the meeting in Washington, D.C., what did you three discuss?
**A.** Pretty much that Holford, who's a professor of statistics, was going to look at the statistics part of the McGovern study. And then I had a draft of my own report, I don't know that I brought it, but I said I would send that to the other two to give them sort of background on where my thinking was. And then Dr. Samet --
**Q.** Dr. Samet or Dr. Borak?
**A.** I'm sorry. I'm sorry. Dr. Borak.
MS. ZIMMERMAN: Both are Jonathans; right?
THE WITNESS: Yeah, that's right.
**A.** So Dr. Borak was particularly interested in looking at the rivaroxaban issue, which we consider a confounding problem.
(Interruption by the reporter.)
THE WITNESS: Confounding issue in the





McGovern study.
**Q.** Dr. Borak was to look at that?
**A.** Yeah.
**Q.** So you would defer to him for his analysis of that?
**A.** Not necessarily, but I think he added something.
**Q.** You don't --
You wouldn't disagree with him; correct?
**A.** That's true.
**Q.** Okay. And you wouldn't disagree with Dr. -- what Dr. Holford has in his report.
**A.** Yes. I said that, yeah.
**Q.** Okay. Have you actually looked at a Bair Hugger?
**A.** I have actually.
**Q.** When?
**A.** Well, a couple times. One, Corey has one in his office, but --
**Q.** In Minneapolis?
**A.** Huh?
**Q.** In Minneapolis?
**A.** In Minneapolis, yeah.
And then I asked a friend of mine, I don't know, maybe a year and a half or so ago, roughly,

who's a thoracic surgeon to walk me through the operating room to see the pre- and post-op and talk about the use of the Bair Hugger warmer which we use.

**Q.** Do you think using the Bair Hugger as a office warmer using it off label?

(Laughter.)

**A.** I don't know about that.

MR. COREY GORDON: You have no idea what goes on in my office.

**Q.** Well have you -- have you -- I mean, have you checked -- have you done any swabs on Corey Gordon's skin to see if he has a higher bioburden than anyone else?

**A.** I don't really have to answer that, do I?

(Laughter.)

**Q.** If you did, I really want you to answer it.

(Laughter.)

**A.** I like your sense of humor.

MR. GOSS: Kind of like walking next to pig pen.

(Laughter.)

MR. COREY GORDON: I don't get no respect.

**Q.** Did you --

Did you look at the Bair Hugger device with a blanket attached?





**A.** Yeah.

**Q.** Okay.

**A.** Yeah.

**Q.** And have you felt the air coming out of the -- underneath the blanket?

**A.** Yeah, you can feel it, yeah. Getting -- The warmth, you mean.

**Q.** Yeah.

**A.** Yeah.

**Q.** You agree that the temperature of the air coming out of the blanket is warmer than the body temperature.

**A.** I think it is. I mean, it's set at, like, 42, 43, and --

**Q.** I mean, because if the air coming out was below body temperature it would actually cool the patient; correct?

**A.** It would cool the patient.

**Q.** Okay. It would be ridiculous to think that the air coming out of the Bair Hugger is below body temperature; correct?

**A.** Yes.

These are getting tough now, these questions.

**Q.** They are, aren't they?





Well there's some experts believe, on the defense side, that the air coming out of the Bair Hugger is less than 36 degrees.

MR. COREY GORDON: Object to the form of the question, that mischaracterizes the evidence, misstates the evidence.

**Q.** Because that would be ridiculous to think that you'd blow cold air on a patient. That would be unethical. Correct?

**A.** These days what we know now, yes.

**Q.** Okay. Now you didn't rely --

Looking at Exhibit 5, in formulating your opinions in this case you did not rely on any of the internal documents provided to you during the Walton case; is that fair?

**A.** That's true.

**Q.** Okay. And in fact would it be fair to say that you probably haven't looked at those documents provided to you in Walton since 2015?

**A.** That's probably true.

**Q.** Okay. So if I asked you what documents are in that set, you would have no idea.

**A.** That's probably right.

**Q.** Okay. Do you believe that 3M gave you all the information necessary to formulate your opinions





in this case?

MR. COREY GORDON: Object to the form of the question.

**A.** I didn't rely on 3M to provide me all the information. I really did much as I can to find what was in the literature in addition to whatever was given.

**Q.** Are you aware that 3M is doing a pilot study in the U.K.?

**A.** I'd heard that in one of the depositions but I don't remember -- I don't know any details, nothing.

**Q.** All right.

MR. ASSAAD: Let's take a break for the court reporter.

THE REPORTER: Thank you.

(Recess taken from 11:29 to 11:43 a.m.)

BY MR. ASSAAD:

**Q.** I just want to go back with respect to Exhibit Number 5. That was attached to your report in Walton. You don't disagree with that; correct?

**A.** I don't remember it actually, I'm sorry to say.

**Q.** So you did a lot of work on Walton; correct?

**A.** I did. I tried to look at that carefully --

**Q.** Okay.

11:43:42 **A.** -- and I just can't remember that.
11:43:45 **Q.** And in fact you -- you know, a lot of the
11:43:48 work you did in Walton, except for, you know, stuff
11:43:51 dealing directly with Walton with the medical records,
11:43:54 you used in your report -- or you had that information
11:43:56 that you used in your report in this case; correct?
11:43:58 **A.** I'm sure there are parts in both, yeah.
11:44:00 **Q.** Okay. I mean, you didn't start from scratch
11:44:06 in this case.
11:44:07 **A.** No.
11:44:07 **Q.** Okay. Do you know how much you billed in
11:44:10 Walton?
11:44:11 **A.** Total?
11:44:11 **Q.** Yes.
11:44:12 **A.** I don't remember. I don't -- Maybe somebody
11:44:15 here has it, but.
11:44:18 **Q.** Well by the way, when did you -- when did
11:44:20 you retire from Virginia Commonwealth University?
11:44:23 **A.** So, formally 2013.
11:44:27 **Q.** 2013. So you were retired by the time you
11:44:29 started the Walton case; correct?
11:44:32 **A.** Well, you know, if you were to ask me why'd
11:44:34 you do that, it was -- a lot of it was timing, you
11:44:37 know, I've always been interested in taking care of
11:44:39 these patients. I've never done really a lot





11:44:42 medical/legal.
11:44:43 **Q.** Well that really wasn't my question.
11:44:44 My question was you were retired by the time
11:44:46 you started the Walton case.
11:44:48 **A.** Yeah, that's right.
11:44:48 **Q.** Okay.
11:44:49 **A.** Right about that time, yeah.
11:44:50 **Q.** Okay. And so after you retired was -- was
11:44:51 your -- was most of your income based on doing the
11:44:54 Walton case?
11:44:54 **A.** No. I was fine without it, and the motive
11:44:59 wasn't income, because I've never really done much of
11:45:02 this. It was just curiosity and timing.
11:45:04 **Q.** So what were your sources of income after
11:45:07 you retired?
11:45:07 **A.** Oh, I have a very good retirement from
11:45:10 TIAA-CREF.
11:45:13 **Q.** I understand you have a retirement plan, but
11:45:15 my question is: Besides your retirement plan, what
11:45:17 other income did you -- do you have besides --
11:45:18 **A.** Besides retirement?
11:45:19 **Q.** Uh-huh.
11:45:20 **A.** Occasionally giving talks, sometimes --
11:45:25 yeah, I guess Social Security, if that's what you're
11:45:29 asking, as well.





11:45:31 **Q.** Would you agree with me that most of your
11:45:33 income that you've received since 2013 was -- was most
11:45:37 likely from working on the Bair Hugger case?
11:45:41 **A.** No, I would disagree with that. I would
11:45:44 guess somewhere a quarter to a third maybe in the last
11:45:52 couple years --
11:45:52 **Q.** Okay.
11:45:52 **A.** -- of the total.
11:45:54 **Q.** Now I'm not talking about your pension
11:45:55 income. I'm talking about non-pension income.
11:45:58 **A.** Oh, of non-pension income, yeah. This --
11:46:00 This is a large portion of that.
11:46:02 **Q.** What percentage?
11:46:05 **A.** Oh, it's probably, you know, except for --
11:46:09 It's huge. It's probably 80 percent or more, yeah.
11:46:13 **Q.** Okay. Can you give me roughly how much
11:46:17 you -- you billed in Walton?
11:46:19 **A.** I'm guessing 90,000, something like that,
11:46:22 but --
11:46:22 **Q.** Okay.
11:46:24 **A.** -- don't hold me to it. Go ask them.
11:46:25 **Q.** Around that, give or take 10,000?
11:46:27 **A.** Go ask them. Yeah.
11:46:28 **Q.** Do you have those invoices still?
11:46:30 **A.** I don't think so, but they do, I think, so





11:46:30 you --
11:46:32 **Q.** Greenberg Traurig?
11:46:33 **A.** Yeah. I would just -- If you need that.
11:46:35 **Q.** Did you bill any time for Johnson?
11:46:38 **A.** Probably, yeah.
11:46:39 **Q.** Do you know how much you billed for Johnson?
11:46:41 **A.** No. I think -- I lumped them together when
11:46:41 I --
11:46:41 **Q.** Okay.
11:46:44 **A.** -- gave you that figure, so -- and I'm not
11:46:46 trying to be cagey, I just don't remember.
11:46:49 **Q.** So basically since two thousand -- since you
11:46:53 began in -- began working on this case --
11:46:53 **A.** Yeah.
11:46:54 **Q.** -- you approximate over $300,000.
11:46:57 **A.** Yeah.
11:47:00 **Q.** And my understanding is you -- you billed
11:47:04 over $300,000 to do a -- a literature review and to
11:47:10 formulate opinions off the literature.
11:47:12 MR. COREY GORDON: Object to the form of
11:47:14 the question.
11:47:14 **A.** Yeah, to -- Yeah. I mean basically I
11:47:17 reviewed the literature, came up with opinions, did my
11:47:20 best to cite all the articles, pro or con.
11:47:24 **Q.** Okay. So the answer to my question is

"correct."

**A.** Yeah. Yeah.

**Q.** Okay.

**A.** Well I just made sure that we're -- we're on the same wavelength.

**Q.** Okay. Did you --

Did you keep an accurate -- accurate time of -- of what you did in this case?

**A.** Yeah. I have the actual hours by month --

**Q.** Okay.

**A.** -- and by day.

**Q.** Are they underestimated hours, or did you work on --

**A.** Oh, no. I -- When I sit down, you know, if it's 12:15 I put 12:15. If I get up for a break at 1, I put 1.

**Q.** Okay. And you also had an assistant that worked on this case; correct?

**A.** Yes.

**Q.** Ms. Briley?

**A.** Yes.

**Q.** And who is she?

**A.** She's been my assistant for a long time, and I don't pay her a salary any more, so she helps me do the legal things that I need done, you know, getting





the manuscripts, writing various drafts of the paper, planning any kind of travel that I might have to do related to the case.

**Q.** Is she a -- like a secretary?

**A.** Yeah, sort of, but a -- more of a senior administrative type secretary, yeah.

**Q.** Does she do any research for you?

**A.** No.

**Q.** Okay.

(Discussion off the stenographic record.)

(Wenzel Exhibits 6 - 7 marked for identification.)

BY MR. ASSAAD:

**Q.** What's been marked as Exhibit Number 6 and Number 7 are invoices provided to the plaintiff in this case from you. Does that look like your invoices?

**A.** Yes.

**Q.** Okay. And these are invoices that you provided to 3M in working on this case; correct? Or their attorneys?

**A.** I provided them to the legal firm.

**Q.** When I say "3M," I'm referring to 3M or their attorneys.

**A.** Okay.





**Q.** So it seems that your first invoice on Exhibit Number 6 is dated December 7th, 2015; correct?

**A.** So I have the righ -- Oh, 6. I'm sorry. So where -- What page are you on?

**Q.** Look on the first page of 6, it's December 7th, 2015. Or that's invoice for Ms. Briley.

**A.** That's for -- That's for Barbara Briley, yeah.

**Q.** Okay. Well if you look on I guess your first invoice, which is dated June 6, 2016 on Exhibit 6?

**A.** Yeah. Let me go through it. I don't know where we are. Oh.

How many pages in are you?

**Q.** About six.

**A.** Okay.

**Q.** Okay. And that's your invoice is for each month from December 2015 to May 2016; correct?

**A.** Should be, yeah.

**Q.** Okay. So basically the first invoice provided to defendants in this -- or to the plaintiffs in this case that we have is for December of 2015; correct?

**A.** Yeah. Looks like that's the first one there.





**Q.** But there are invoices that you've worked on a Bair Hugger case prior to December 2015.

**A.** You're talking about the earlier cases?

**Q.** Walton and Johnson.

**A.** Yeah, that's right.

**Q.** Okay. And based on my calculations, the invoices that were provided to us from you total about $213,000. Does that sound about right?

**A.** That's about right, I think. I don't know exactly, but it sounds right.

**Q.** And for Ms. Briley it was $6,860. That sound about right?

**A.** I don't know. I didn't add up hers, but.

**Q.** Okay. But you're not going to disagree with the invoices; correct?

**A.** No.

**Q.** Does she --

Does she keep all the money that she charges for?

**A.** Yeah. It all -- It goes directly to her.

**Q.** Okay.

**A.** I tried to keep that separate.

**Q.** And this money goes directly to you, it doesn't go to Virginia Commonwealth University; correct?

11:52:36 **A.** That's true.
11:52:37 **Q.** Okay. Do you have a company that it goes
11:52:39 to, or it just goes to you personally?
11:52:42 **A.** No.
11:52:42 **Q.** Okay.
11:52:42 **A.** I haven't become sophisticated like that.
11:52:44 **Q.** And it seems like you spent -- the total
11:52:46 number of hours spent is 380 hours -- 380.75 hours.
11:52:59 That sound about right?
11:53:01 **A.** Probably right.
11:53:02 **Q.** Okay. And Ms. Briley spent about 196 hours;
11:53:06 correct?
11:53:06 **A.** Well I didn't add that up, so I'm assuming
11:53:07 you're right.
11:53:08 **Q.** Okay.
11:53:09 **A.** If it matches this, you know.
11:53:10 **Q.** Okay. So that's the total of, you know,
11:53:12 over 500 hours between you and Ms. Briley.
11:53:16 **A.** Umm-hmm.
11:53:16 **Q.** Is that correct?
11:53:17 **A.** Yeah.
11:53:19 **Q.** Okay. And approximately how many hours did
11:53:19 you spend on the Walton-Johnson case?
11:53:23 **A.** I don't know. I mean, that's why I said the
11:53:25 total might have been close to $90,000, so.





11:53:28 **Q.** And you charge how much per hour?
11:53:30 **A.** Six hundred.
11:53:30 **Q.** So 90,000 divided by 600 equals about 150
11:53:35 hours. This sound about right, give or take?
11:53:37 **A.** That sounds about right.
11:53:38 **Q.** Okay. So so far between you and M --
11:53:40 Did Ms. Briley work on the Walton case?
11:53:45 **A.** I think she did, yes.
11:53:49 **Q.** Do you know how many hours that she billed?
11:53:51 **A.** I don't, actually. Don't remember that.
11:54:06 **Q.** So between you and Ms. Briley, and not
11:54:09 counting her time on Walton, the two of you spent over
11:54:12 720 hours on this case.
11:54:15 **A.** Yeah. Sounds about right.
11:54:17 **Q.** Okay. Did you ever recommend to 3M to --
11:54:22 let's -- to do a study?
11:54:24 **A.** No.
11:54:25 **Q.** Okay. Why not?
11:54:29 **A.** I haven't met with 3M.
11:54:30 **Q.** Or their attorneys.
11:54:32 **A.** Ask the attorneys to do a study?
11:54:35 **Q.** I mean, hey, why don't you recommend -- you
11:54:36 should recommend to 3M to do a study?
11:54:38 **A.** I have never asked them that.
11:54:40 **Q.** Okay. You're not an expert in aerobiology;





11:55:00 correct?
11:55:01 **A.** I'm not an expert in aerobiology.
11:55:03 **Q.** You're not an expert in microbiology;
11:55:05 correct?
11:55:06 **A.** In what?
11:55:06 **Q.** Microbiology?
11:55:07 **A.** Well, I'd caution you there. I mean, I
11:55:10 think microbiology is the basis of infectious
11:55:13 diseases, and in that interface between micro and
11:55:17 infectious disease I am an expert.
11:55:19 **Q.** But you're not an microbiologist.
11:55:20 **A.** I'm not a --
11:55:21 I don't have a degree in microbiology.
11:55:23 **Q.** Okay. You don't consider yourself an expert
11:55:29 in orthopedics; correct?
11:55:32 **A.** Only the interface, again, between
11:55:34 orthopedics and infectious diseases. I'm not an
11:55:39 orthopedic surgeon.
11:55:40 **Q.** You don't consider yourself an expert in
11:55:42 medical device design; correct?
11:55:43 **A.** That's true.
11:55:44 **Q.** You don't consider yourself an expert in
11:55:45 medical device warnings; correct?
11:55:47 **A.** Warnings, no.
11:55:48 **Q.** You don't consider yourself an expert in





11:55:50 patient warming; correct?
11:55:50 **A.** In what?
11:55:51 **Q.** Patient warming.
11:55:52 **A.** A expert in patient warming?
11:55:54 **Q.** Yeah.
11:55:55 **A.** Only as it is influenced in this case with
11:55:58 the infectious disease part, but not --
11:56:00 **Q.** And everything that you opine is going to
11:56:03 be --
11:56:03 **A.** -- warming.
11:56:04 **Q.** -- is going to be based on a literature
11:56:05 review and not your own personal --
11:56:10 **A.** That's true.
11:56:10 **Q.** -- directed research.
11:56:11 **A.** Yes, that's --
11:56:11 (Interruption by the reporter.)
11:56:11 (Discussion off the stenographic
11:56:14 record.)
11:56:14 **Q.** Correct?
11:56:14 **A.** Yes.
11:56:15 **Q.** Okay. You're not an expert in operating
11:56:17 room design; correct?
11:56:18 **A.** Correct.
11:56:19 **Q.** Have you read any of the ASHRAE articles or
11:56:24 chapters regarding operating room design?

11:56:26 **A.** Don't think so.
11:56:28 **Q.** Are you aware that it is estimated between
11:56:34 one million to 900 million skin squames are shed
11:56:40 during a two- to four-hour surgery?
11:56:42 MR. COREY GORDON: Object to the form of
11:56:44 the question.
11:56:44 **A.** So I didn't go to the primary literature but
11:56:47 I've seen that in a couple depositions.
11:56:49 **Q.** Do you disagree with that?
11:56:50 **A.** No reason to disagree or agree.
11:56:52 **Q.** Okay. You have no experience in
11:57:02 operating-room airflow; correct?
11:57:05 **A.** Any experience, no.
11:57:06 **Q.** Okay. You don't consider you're an expert
11:57:07 in operating airflow?
11:57:09 **A.** That's true.
11:57:10 **Q.** I think I've asked you this before, but
11:57:11 you're not an expert in particle flow; correct?
11:57:13 **A.** In particle flow, no. I'm not.
11:57:16 **Q.** Do you agree with me that Dr. Elghobashi is
11:57:18 an expert in particle flow and turbulent air?
11:57:21 MR. COREY GORDON: Object to the form of
11:57:22 the question, lack of foundation.
11:57:22 **A.** I have no idea of his expertise.
11:57:24 **Q.** Well you've rea -- you've seen his report;





11:57:26 correct?
11:57:26 **A.** Yeah. I didn't understand most of it.
11:57:26 **Q.** Did you --
11:57:27 And you didn't have an opportunity to
11:57:29 compare our expert's report to defense expert's
11:57:31 report; did you?
11:57:32 **A.** No. Only what I saw on Science Day,
11:57:35 basically.
11:57:36 **Q.** Okay. And you're not an expert in turbulent
11:57:44 flow; correct?
11:57:45 **A.** In turbulent flow? No, I'm not an expert in
11:57:48 turbulent flow.
11:57:49 **Q.** Okay. Have you read the Complaint in this
11:58:01 case?
11:58:06 **A.** I think I may have read it at the time of
11:58:09 Walton, and -- I remember seeing that.
11:58:12 **Q.** Okay.
11:58:13 **A.** More recently I don't think I looked at
11:58:14 anything.
11:58:15 **Q.** What is your understanding of plaintiffs'
11:58:17 claims in this case with respect to the mechanism of
11:58:20 injury of a Bair Hugger causing a -- an infection?
11:58:27 **A.** My understanding is that the plaintiffs are
11:58:30 saying that there is heat generated from the Bair
11:58:36 Hugger, and it creates currents, particularly --





11:58:41 including, at least, a downflow current towards the
11:58:44 floor, whipping up some kind of particles into the air
11:58:51 near the operative site, and therefore they think that
11:58:56 the Bair Hugger, having done that, relates to
11:59:01 infections. That's my understanding.
11:59:03 **Q.** You don't disagree that the Bair Hugger
11:59:04 generates heat; correct?
11:59:06 **A.** It does generate some heat.
11:59:08 **Q.** Well do you know how much heat?
11:59:10 **A.** I don't.
11:59:10 **Q.** Okay. Well you used the term "some." Do
11:59:13 you know -- You're just -- you're not --
11:59:15 You're not quantifying it; correct?
11:59:16 **A.** I'm not.
11:59:17 **Q.** Okay. You do agree that the Bair Hugger,
11:59:20 the holes are facing down; correct?
11:59:22 **A.** Yes.
11:59:22 **Q.** Onto the patient?
11:59:23 **A.** Yes.
11:59:24 **Q.** In an orthopedic surgery.
11:59:25 **A.** Yes.
11:59:25 **Q.** Okay. So you do agree that it creates
11:59:27 current, air currents.
11:59:29 **A.** I think it does.
11:59:30 **Q.** Okay. And you agree that --





11:59:37 Do you know what the first law of
11:59:38 thermodynamics is?
11:59:39 **A.** No. I know you like to ask that question,
11:59:42 but I don't know it.
11:59:44 **Q.** How do you know I like to ask that question?
11:59:46 **A.** Somewhere in -- you were deposing somebody
11:59:48 and it was one of your earlier questions.
11:59:50 **Q.** Okay. Do you agree that hot air is less
11:59:54 dense than cold air? If you know.
11:59:57 **A.** Yes, I think. Less dense, yes.
12:00:01 **Q.** You've seen a hot air balloon; correct?
12:00:04 **A.** Yes.
12:00:04 **Q.** Okay. And hot air balloons actually rise;
12:00:05 correct?
12:00:06 **A.** Yeah, they do.
12:00:07 **Q.** Okay. You're not going to disagree with the
12:00:08 laws of thermodynamics; are you?
12:00:10 **A.** I have no idea what the law of
12:00:11 thermodynamics is.
12:00:12 **Q.** Okay. Okay. You're going to defer to the
12:00:13 engineers in this case.
12:00:14 **A.** To you.
12:00:15 **Q.** To me? You'd defer --
12:00:15 **A.** Yeah.
12:00:16 **Q.** -- to me as well. Okay.

Unfortunately, I can't testify.
(Laughter.)
**Q.** Which is a good thing, because I think Corey would love to take my deposition.
And you agree with me that skin squames have a mass; correct?
**A.** "Have a mass"? You mean they're not just energy, is that what you're asking?
**Q.** Yes.
**A.** Yes.
**Q.** Okay. And you agree with me that gravity exists in an operating room; correct?
**A.** It exists everywhere.
**Q.** Okay. Now just so I understand your opinion, assuming that the plaintiffs' engineering theory is correct that the hot air causes contaminated air from underneath the operating table to rise to above the operating room surgical table, is it correct that your opinion is going to be that since you believe that most of the surgical-site infections are caused by the patient's flora, that the effect of the Bair Hugger is irrelevant?
MR. COREY GORDON: Object to the form of the question, incomplete hypothetical.
**A.** I've told you separately I think most





infections come from the patient flora, no question. Now you're asking me a hypothetical assuming that everything that the plaintiffs say is correct, would that have an influence. And it might, but that's an assumption.
**Q.** So -- So if the plaintiffs are correct that the Bair Hugger causes contaminants from underneath the operating room floor to actually go into the -- above and into the surgical site, that may have an effect on your opinion?
**A.** If everything that you say was validated, and I don't -- I don't think we're there yet, in this hypothetical situation, it might contribute. We have no data, I think, to really convince people that the Bair Hugger actually leads to infections.
**Q.** Okay. How do we get there?
**A.** How do we get the data?
**Q.** Yeah.
**A.** Well what I've tried to do is do the following.
**Q.** Well I understand what you did. You said we're not there yet. That was your -- That was your answer. So how do we -- What would you do today to determine the answer to that question? Not looking at literature in the past, but what would you do today?





**A.** So if -- if there, you know, was a study that was being planned, one of the things I would do is link the -- what was found in the air, microbiologically, with what was found somewhere else, not on the patient flora, if you could do that. Because you're positing that things come up from the floor. And link what's on the floor, link what's in the air and link what's in the patient's wound, and show me it's the same -- pick a organism, Staph aureus, with the same fingerprint.
**Q.** Okay. And how many patients do you think you would need to do that study?
**A.** I don't know.
**Q.** Like -- Like 50, a thousand, 10,000?
MR. COREY GORDON: Object to the form of the question, lack of foundation.
**A.** Well --
**Q.** And I'm talking about with respect to a total hip or total knee arthroplasty.
**A.** You'd need a lot of patients to show -- to show that. And you have to do a multi-centered study, and we'll get a statistician to look at what you'd expect. But I, off the cuff, wouldn't come up with an answer.
**Q.** So you'd want to do microbiological sampling





of, like, what's underneath the operating room table; correct?
**A.** Yeah, because you said that's where it starts.
**Q.** And you want to do microbio -- microbiological sampling of the patient's flora in the wound.
**A.** Right.
**Q.** Okay. And I think you said one other microbiologic sample.
**A.** It would have to be in the air --
**Q.** Okay.
**A.** -- because you said it comes up in the air, in your hypothetical.
**Q.** So what's in the air before you turn the Bair Hugger on; correct?
**A.** Before and during.
**Q.** Okay, during.
And then you want to also determine which patients obtained infections; correct?
**A.** Right. Right.
**Q.** And so for total hip and total knee you might need 10,000 patients.
**A.** A lot of patients.
**Q.** Okay. And so that study would be very,

very, very expensive; correct?
**A.** Ten thousand patient would be expensive.
**Q.** Okay. And to do all that microbiological sampling would be expensive too.
**A.** Right. Truth is costly sometimes.
**Q.** Okay. And -- And you agree with me, based on your experience of doing research, that probably the only person that would ever fund a study such like that or -- would be the manufacturer of the device.
MR. COREY GORDON: Object to the form of the question.
**A.** I'm not sure if NI -- it'd take awhile to get NIH involved in that, but at least I'd give it a try if I were really going to go into that.
**Q.** But the NIH, you know --
**A.** But typically they don't --
**Q.** -- funds very little studies.
**A.** Typically they don't get into devices and --
But the mechanism might be important as a general surgery issue. Forget just hips and, you know, prostheses.
So if you could expand it, I wouldn't be surprised that, you know, a well written, general surgery person could maybe convince them to do -- to look at it.





**Q.** When you say "the mechanism," what do you mean by "the mechanism"?
**A.** In other words, if the question is what's the pathogenesis of surgical-site infections, that's what I would be asking in the front end. And if you said it's not just that we're going to look at hips and knees, because the numbers might be very high, but let's look at some general surgery patients.
The reason, for example, that Kurz and Melling looked at the patients they did, particularly Kurz, because of the high infection rate with colorectal surgery.
**Q.** But colorectal is a -- is a -- is considered a dirty surgery; correct?
**A.** It is. It's clean contaminated.
**Q.** Clea -- Okay. Well there's clean, there's clean contaminated, and then there is --
What's the third one?
**A.** Contaminated where you've cut across a tube, essentially. So in other words, gallbladder duct, something like that.
**Q.** So cutting into the -- the colorectal area is not considered contaminated?
**A.** I think it depends on how much spillage there is.





**Q.** Okay.
**A.** And then contaminated obviously if there's already --
**Q.** Okay.
**A.** -- an infection.
**Q.** So you want to look at the mechanism of injury with respec -- look at the mechanisms across the board; correct? Is that what I'm understanding?
**A.** No. If you were going to design a study, you know, my label would be what's the pathogenesis of surgical-site infections. And I think, you know, so far what I've learned is that it's the patient's microbiome that's the source.
Now what I think you're getting at is a very interesting question. What's -- How does it get from the source to the wound? And you're positing, in your hypothetical, that maybe it's not the patient's microbiome but it's something on the base of the floor being wafted up. So I would like to try to put that to rest one way or another.
That make sense? I'm trying to...
**Q.** You agree that implant surgeries are more susceptible to infection than non-implant surgeries.
**A.** Well let's pause for a second. I'm not sure the pathogenesis of the initiation is different, but





once the infection is present, once you have the biofilm, then it's -- it's much harder to cure and almost always you have to then replace the -- the joint because the foreign body is going to hold the organisms there.
But if you said what's the initiation phase I think you still start with the flora, patient flora. And I think the patient's flora is there at the time of surgery, at the time of the incision. That's my current thinking.
**Q.** Okay.
**A.** And then once the infection -- because I know that you've discussed with other people, you know, biofilm. That's a different story. Once you have that, the therapy and then the -- the late pathogenesis, there's no question, if that's what you're asking, is different in a device-related infection than a non-device-related infection.
**Q.** So is it your opinion that the infection dose for a implant infection is the same for a superficial wound infection? Is the infection dose --
**A.** You know we know so little about infectious dose, but I think the initiation might be -- I don't know. I don't know how to answer that question for sure.

12:09:23 **Q.** Well if you don't know you can say you don't know.
12:09:25 **A.** Yeah. So I don't know, --
12:09:25 **Q.** All right.
12:09:26 **A.** -- there aren't...
12:09:27 **Q.** That's fine.
12:09:28 **A.** But I thought we were talking hypotheticals, and that's --
12:09:30 **Q.** Well you mentioned -- you discussed the rabbit studies and the mice studies; correct?
12:09:35 **A.** Yeah. Right.
12:09:36 **Q.** And many of those studies, and we can go through them if you want, but let's try to get here --
12:09:41 **A.** Yeah. No. That's --
12:09:43 **Q.** -- out of here by six o'clock.
12:09:45 **A.** Yeah. No. That's fine. Yeah.
12:09:46 **Q.** Most of those studies indicated that when there is an implant the infectious dose is much less than when there's no implant.
12:09:51 **A.** I think in general that's true.
12:09:51 **Q.** Okay.
12:09:52 **A.** There's probably less based on the animal studies, yeah.
12:09:56 **Q.** And in fact if you looked at the rabbit study, and let's go to --





12:10:14 **A.** I'm thinking you're probably looking for the end of the...
12:10:18 **Q.** Yeah, you're right.
12:10:19 (Interruption by the reporter.)
12:10:23 **A.** The end of the report.
12:10:23 **Q.** Okay. Page 77.
12:10:25 **A.** Yeah.
12:10:25 **Q.** Okay. So --
12:10:26 And you've looked at these studies; correct?
12:10:29 **A.** I have. That's where I made the table from, and...
12:10:31 **Q.** Okay.
12:10:33 **A.** And this doesn't -- I don't mean to imply it's a comprehensive look, but it's a sample.
12:10:34 And what I come away with is the infecting dose varies by which animal and which mechanism that you're infecting the animal.
12:10:36 **Q.** But in the Southwood study of 1985, when a medullary inoculation with prosthesis, which means they actually kept the prosthesis in; correct?
12:10:40 **A.** Right.
12:10:43 **Q.** Okay. The other ones they did not keep the prosthesis in; correct? The other three --
12:10:47 They had four different routes of infection; correct?
12:10:49
12:10:53
12:10:56
12:10:59
12:10:59
12:11:01
12:11:04
12:11:06





12:11:07 **A.** I didn't count them all, but they're -- you know, they're -- they're numerous, yeah.
12:11:09 **Q.** Okay.
12:11:12 **A.** This was the intravenous study. Is that the one you're referring to?
12:11:13 **Q.** Yeah. Hold on one second, just pulling it up so that we're on the same page.
12:11:19 They had four groups; correct?
12:11:20 **A.** I don't remember exactly, but.
12:11:22 **Q.** You have route of infection number IV here at -- near the top; correct?
12:11:35 **A.** Okay. All right.
12:11:38 **Q.** And --
12:11:40 **A.** Oh, I see what you're saying. These four, yeah.
12:11:42 **Q.** And --
12:11:43 (Discussion off the stenographic record.)
12:11:44 MR. COREY GORDON: Is that roman numeral, or is that intravenous?
12:11:45 THE WITNESS: Oh, that's -- No, it's "I-V," intravenous.
12:11:47 MR. ASSAAD: Oh, it's "I-V"? Okay.
12:11:48 THE WITNESS: Yeah. That's why I thought you meant the studies here.
12:11:52 BY MR. ASSAAD:





12:12:07 **Q.** The reason why I ask is they also have groups I, II, III, IV in Roman numerals.
12:12:09 THE WITNESS: I'm glad you said something there [to counsel].
12:12:12 (Discussion off the stenographic record.)
12:12:14 (Wenzel Exhibit 8 marked for identification.)
12:12:14 BY MR. ASSAAD:
12:12:14 **Q.** Doctor, Exhibit Number 8 is the -- is the Southwood article referred on page 77 of your report of Exhibit 1; correct?
12:12:42 **A.** Yes.
12:12:45 **Q.** Okay. Let's look at --
12:12:48 Let's explain to the ladies and gentlemen of the jury what $ID_{50}$ means.
12:12:49 **A.** It's the dose of organism that will infect 50 percent of the subjects --
12:12:49 **Q.** Okay.
12:12:53 **A.** -- as opposed to the dose, you know, which required to infect 10 percent or a hundred percent.
12:12:55 **Q.** And a dose would be considered a CFU?
12:12:58 **A.** In this case, yes.
12:13:03 **Q.** Okay. So in this case it would be a CFU; correct?
12:13:07
12:13:08
12:13:11
12:13:14
12:13:16
12:13:17
12:13:20
12:13:20

12:13:21 **Q.** Let's turn to Figure 2 on page 230 of
12:13:23 Exhibit 8. It's the second page.
12:13:26 **A.** Table 2, or Figure 2?
12:13:28 **Q.** Or Figure 2. I'm sorry.
12:13:30 And they talk about four different types of
12:13:33 ways they infected the rabbit; correct?
12:13:37 **A.** Yeah. I'm trying to remember the study.
12:13:39 Yeah.
12:13:39 **Q.** One was --
12:13:40 The first one was medullary, they infected
12:13:42 the actual implant; correct?
12:13:44 **A.** Yes.
12:13:45 **Q.** Then they did medullary but they took out
12:13:46 the prosthesis; correct?
12:13:48 **A.** Yes.
12:13:49 **Q.** And then they did a delayed intravenous and
12:13:51 an intravenous; correct?
12:13:52 **A.** Yeah.
12:13:53 **Q.** Okay. And let's look down at the
12:13:56 calculations they did, and it says: "In Group I
12:13:59 (medullary peroperative inoculation) $ID_{50}$ equals 1 .3
12:14:06 times 10 to the 1.114"; correct?
12:14:10 **A.** Where are we?
12:14:11 **Q.** The description of Figure 2. The small
12:14:14 writing right below the figures.





12:14:16 **A.** Oh, I see. Okay. The range of inocula?
12:14:20 Yeah. (Witness reviewing exhibit.)
12:14:21 **Q.** Okay. That means how much bacteria --
12:14:23 what's the effective dose for 50 percent when you --
12:14:29 you add back -- add CFUs to the implant; correct?
12:14:33 **A.** Yeah.
12:14:34 **Q.** Okay. Have you calculated what 1.3 times 10
12:14:37 to the 1.114 is?
12:14:38 **A.** No. It's low. It's a small number.
12:14:41 **Q.** Uh-huh. I'm going to calculate it for you,
12:14:44 let me see if you agree with me.
12:14:46 **A.** It's probably 15 or 20.
12:14:48 **Q.** 1.3 times 10 to the 1.114. [Calculating.]
12:15:01 About 17; correct?
12:15:02 **A.** I was pretty close.
12:15:03 **Q.** Okay. Or, I'm sorry, 1.7. Is it 1.7? I'm
12:15:08 sorry. Let me calculate it again. [Calculating.]
12:15:16 It's below 20; correct? Whatever it is, it
12:15:25 is; correct?
12:15:26 **A.** It's low.
12:15:26 **Q.** That's a very low number; correct?
12:15:30 **A.** Yeah.
12:15:30 **Q.** Okay. Compared to the in -- the infection
12:15:32 dose for groups II, III and IV, which are 10 to the 5;
12:15:37 correct?





12:15:38 **A.** Yeah.
12:15:38 **Q.** Okay. Which are very large numbers;
12:15:42 correct?
12:15:42 **A.** They're big numbers. Bigger than 10 to the
12:15:45 --
12:15:45 **Q.** So you agree with me then when -- at least
12:15:47 in the rabbit case, that when -- the infective dose
12:15:53 when a bacteria gets on the implant is much lower than
12:15:58 when it's not on the implant.
12:16:00 **A.** That's what the study showed.
12:16:02 **Q.** And do you disagree with that study?
12:16:03 **A.** No.
12:16:04 **Q.** Okay. And in fact you agree with me that
12:16:09 one skin squame can carry, you know, multiple CFUs.
12:16:12 **A.** I think I've read that, that they can car --
12:16:15 can carry, sometimes, several, up to three or four or
12:16:19 something.
12:16:20 **Q.** Even more.
12:16:21 MR. COREY GORDON: Object to the form of
12:16:22 the question.
12:16:23 **Q.** I mean, you agree with me that there is 10
12:16:24 times more bacteria on our skin than actual skin
12:16:27 cells.
12:16:28 **A.** Than actual what?
12:16:29 **Q.** Than our skin cells.





12:16:30 **A.** Well it's not just skin, the -- what I cited
12:16:33 was the total flora on the body.
12:16:35 **Q.** I understand. But the total flora, there's
12:16:37 10 times more flora on our skin than actual skin
12:16:41 cells.
12:16:41 **A.** Yeah.
12:16:41 **Q.** Okay. And the flora is bacteria; correct?
12:16:45 **A.** When you say flora, it's bacteria, it's
12:16:48 fungus --
12:16:48 **Q.** Okay.
12:16:49 **A.** -- some parts of the body it's virus.
12:16:50 **Q.** Okay. So in fact you could say that for
12:16:54 every skin cell there's -- there's 10 flora, on
12:16:59 average.
12:17:02 **A.** So for every skin cell there are 10 -- Yeah.
12:17:07 **Q.** Okay.
12:17:07 **A.** There might be more bacteria, yeah.
12:17:09 **Q.** So in fact a skin squame could carry more
12:17:11 than three or four bacteria.
12:17:14 **A.** Okay. I haven't looked at that recently,
12:17:16 but yeah.
12:17:17 **Q.** But the math -- the math makes sense;
12:17:19 correct?
12:17:19 **A.** Okay.
12:17:19 **Q.** Do you agree?

12:17:20 **A.** I think I've seen up to --
12:17:22 **Q.** Okay.
12:17:23 **A.** -- four or five.
12:17:24 **Q.** Okay. And some might have a cluster on it
12:17:26 that might have 20, 30.
12:17:28 **A.** Yeah, I don't know that.
12:17:29 **Q.** Okay. I mean, bacteria go into clusters;
12:17:33 correct?
12:17:33 **A.** They do clump.
12:17:35 **Q.** Okay. And they could clump as few as 3 and
12:17:36 as many as hundreds.
12:17:38 **A.** Yeah, I don't know about hundreds. I just
12:17:40 -- I just can't say I know that, but maybe.
12:17:44 **Q.** More than ten.
12:17:45 **A.** Yeah.
12:17:45 **Q.** Probably more than twenty.
12:17:46 **A.** I don't know.
12:17:48 **Q.** Okay. So there is a difference with respect
12:17:53 to the infection dose of an implant if the bacteria
12:17:58 lands on an implant as compared to the -- if the
12:18:00 bacteria lands on -- on skin.
12:18:02 **A.** That's not what they really showed. They
12:18:04 didn't say "land on." They injected it.
12:18:07 **Q.** Okay. Well --
12:18:08 **A.** That's different. Surgeons don't go in and





12:18:11 shoot a number of organisms into the joint.
12:18:15 **Q.** Well you agree with me that -- forget about
12:18:18 the way it -- the bacteria gets there, okay, whether
12:18:21 or not it's -- it's injected. I mean, the bacteria
12:18:23 got to the joint in this case; correct? To the -- the
12:18:27 prosthesis.
12:18:28 **A.** But how can I forget how they got there?
12:18:28 **Q.** Okay.
12:18:30 **A.** I'm not sure --
12:18:31 **Q.** So is that a limitation of the study?
12:18:34 **A.** Oh. Well if you want to posit that the air
12:18:37 is important, nobody has done the infectious dose by
12:18:41 the air.
12:18:43 **Q.** Well that would be unethical, wouldn't it,
12:18:46 in a human?
12:18:46 **A.** Well that would be unethical in a human, but
12:18:49 you could count, in the study that I was proposing, or
12:18:52 in another study, show me that one organism in the
12:18:55 air, a markered orga -- markered species that landed
12:19:01 later into the wound, not start with the wound and go
12:19:01 out, --
12:19:01 **Q.** Let me ask you this --
12:19:04 **A.** -- and then caused an infection with that
12:19:06 same --
12:19:06 **Q.** Okay.





12:19:06 **A.** -- genus and species and same fingerprint.
12:19:10 **Q.** Let me ask you this question.
12:19:12 **A.** Yeah.
12:19:14 **Q.** If Darouiche's study, the one that came out
12:19:17 recently which you emailed him about. Do you recall
12:19:19 that?
12:19:20 **A.** Yeah.
12:19:20 **Q.** Okay. He did a microbiology study and it
12:19:21 indicated that the -- the -- the bacteria came from
12:19:26 the air, you know, because of the increased bacterial
12:19:30 load over -- over the surgical site. Would that
12:19:32 change your opinion in this case?
12:19:34 **A.** What he showed was a correlation between
12:19:38 particles and bacteria and the four infections, and he
12:19:43 modeled that to get the correlation.
12:19:45 **Q.** And your criticism of him is that he didn't
12:19:48 do any microbiological testing.
12:19:49 **A.** That's one, yeah, sure. I think that's
12:19:51 important.
12:19:52 **Q.** Because you're not sure whether the bacteria
12:19:54 came from the flora or from the air; correct? The
12:19:57 patient's flora or the air.
12:19:58 **A.** Yeah.
12:19:58 **Q.** Okay. If he did do microbiological testing
12:20:00 and indicated that the bacteria that caused the





12:20:02 infections came from the bacteria that was in the air,
12:20:04 would that change your opinion with respect to whether
12:20:07 or not bacterial load in the air has a -- has a impact
12:20:10 on periprosthetic joint infections?
12:20:12 **A.** Well --
12:20:12 MR. COREY GORDON: Object to the form of
12:20:12 the question, --
12:20:12 **A.** Yeah.
12:20:14 MR. COREY GORDON: -- misstate --
12:20:15 mischaracterizes his testimony.
12:20:16 THE WITNESS: Thank you. I didn't mean to
12:20:17 interrupt, but.
12:20:18 **A.** So one of the things you would like to know
12:20:21 is if there's an organism in the air and if we did
12:20:25 this hypothetical study where we actually had good
12:20:29 microbiology; did it start, first of all, in the flora
12:20:32 of the patient, the microbiome, somehow get into the
12:20:35 air -- I mean, I can imagine how that might happen,
12:20:38 and then land -- or are we talking about a totally
12:20:42 different organism that started on the ground, which
12:20:45 is what you postulated initially, got whipped up by a
12:20:49 device and then hung over the wound and then caused
12:20:54 the infection.
12:20:57 **Q.** Are you asking me a question?
12:20:59 **A.** Well, no. I'm just trying to answer you.

12:21:01 **Q.** Well let's see -- let's go to the Darouiche
12:21:04 article just a couple things.
12:21:05 **A.** Okay.
12:21:05 **Q.** You do understand that he found a
12:21:07 correlation between bacterial load in the air and
12:21:14 periprosthetic joint infections, but no correlation
12:21:16 with superficial wound infections.
12:21:18 **A.** That's what he said, yeah.
12:21:20 **Q.** Do you agree with that?
12:21:20 **A.** Yeah. No, he said that.
12:21:22 **Q.** Okay. But do you have any disagreement of
12:21:23 that, --
12:21:25 MR. COREY GORDON: Object to the form of
12:21:25 the question.
12:21:25 **Q.** -- or criticism of that?
12:21:27 **A.** He's reporting what he found, and I'm saying
12:21:29 if that's what he reported, that's what we'll go with.
12:21:31 **Q.** Well, doctor, you've done a huge literature
12:21:34 review and you've agreed with some articles, you've
12:21:37 disagreed with some articles. I'm asking: Do you
12:21:39 disagree with that conclusion?
12:21:40 **A.** On his? No.
12:21:41 **Q.** Okay.
12:21:41 **A.** I mean, that's what he found.
12:21:42 **Q.** Okay. And you don't disagree with it.





12:21:44 **A.** Yeah.
12:21:44 **Q.** Okay. So you agree that the bacterial
12:22:04 sampling over the surgical site in the Darouiche study
12:22:07 has a direct correlation with periprosthetic joint
12:22:11 infection, you just don't know where that bacteria
12:22:13 came from. Is that correct?
12:22:15 MR. COREY GORDON: Object to the form of
12:22:16 the question.
12:22:16 **A.** I surely don't know where the bacteria came
12:22:19 from, and he certainly didn't match it to his four
12:22:23 infections. It's a very small number of infections,
12:22:25 but he didn't match it.
12:22:27 **Q.** But we do know that when the bacterial load,
12:22:29 the CFUs were increased over the -- over the surgical
12:22:33 site that there was a statistically significant
12:22:36 increase in periprosthetic joint infections; correct?
12:22:38 **A.** That was his correlation, absolutely
12:22:40 correct.
12:22:40 **Q.** And you don't disagree with that.
12:22:41 **A.** No.
12:22:42 **Q.** Okay. Your -- Your criticism is you don't
12:22:46 know whether that bacteria came from the patient's
12:22:48 flora or from somewhere else, and there needs to be
12:22:52 further testing to determine that.
12:22:53 **A.** Has to be a lot more testing to know whether





12:22:56 or not any of those bacteria he found were involved in
12:23:00 the infections.
12:23:01 **Q.** Okay. So we need to do microbiological
12:23:04 testing. That's your criticism.
12:23:06 **A.** Absolutely.
12:23:07 **Q.** Okay.
12:23:07 **A.** And, you know --
12:23:07 **Q.** Okay.
12:23:08 **A.** -- what -- what, three Staph and one mixed
12:23:11 infection.
12:23:40 (Discussion off the stenographic record.)
12:23:47 MR. ASSAAD: Let's take a break for lunch,
12:23:49 guys.
12:23:50 THE WITNESS: Okay.
12:23:52 THE REPORTER: Off the record, please.
12:23:55 (Luncheon recess taken at
approximately 12:23 p.m.)





AFTERNOON SESSION
(Deposition reconvened at
approximately 12:53 p.m.)
BY MR. ASSAAD:
12:53:42 **Q.** Are you ready to continue, doctor?
12:53:46 **A.** Sure. Thank you.
12:53:47 **Q.** Let's go to page 77 of your report regarding
12:53:50 the animal studies.
12:53:53 **A.** Okay.
12:53:54 **Q.** And you cited these studies because you
12:53:56 believe they help you formulate your opinion; correct?
12:53:58 **A.** Yes.
12:53:59 **Q.** And you believe that they're authoritative;
12:54:00 correct?
12:54:01 **A.** Yes.
12:54:01 **Q.** Okay. Let's go to the New Zealand study of
12:54:07 white rabbits?
12:54:09 MR. COREY GORDON: Exhibit 8?
12:54:10 **A.** Oh, Craig? Okay.
12:54:14 MR. COREY GORDON: Oh. I'm sorry.
12:54:14 **Q.** And that's a -- They used 10 animals, and
12:54:17 they inoculated the -- the rabbits with 10 times 5 to
12:54:21 10 times 8 CFUs; correct?
12:54:23 **A.** Yeah, I have 10 to the 2, 10 to the 4.
12:54:28 Maybe I missed that somewhere.

12:54:30 **Q.** The third one down, New Zealand --
12:54:30 **A.** Oh, third one down.
12:54:30 **Q.** Yes.
12:54:30 **A.** Oh, okay.
12:54:32 **Q.** I'm sorry, that's the second New Zealand.
12:54:34 **A.** All right. Okay.
12:54:35 **Q.** New Zealand likes their rabbits, I guess, huh?
12:54:37 **A.** Yeah. Okay. Got it.
12:54:39 **Q.** So you agree that study wasn't -- it was just to show the mechanism of these implants getting infected, they didn't look at inoculation dose.
12:54:48 **A.** Well a lot of studies in fact are trying to get as high a infected dose so they can actually track what's going on with these type of infections rather than scaling up the dose to know exactly what the $ID_{50}$ is, for example.
12:55:04 **Q.** Exactly.
12:55:04 And this study, if you recall, they were looking about ho -- tracking the infection and they did MRIs and everything. Do you recall?
12:55:11 **A.** Umm-hmm.
12:55:14 **Q.** "Yes"?
12:55:14 **A.** Yes.
12:55:15 **Q.** Okay.





12:55:28 (Discussion off the stenographic record.)
12:55:28 (Wenzel Exhibit 9 marked for identification.)
12:55:35 (Discussion off the stenographic record.)
12:55:35 BY MR. ASSAAD:
12:55:35 **Q.** Doctor, you've read this study; correct?
12:55:37 **A.** I have.
12:55:38 **Q.** And you relied upon this study; correct?
12:55:41 **A.** I did.
12:55:41 **Q.** Okay. Let's go to the "Discussion" section on page 3 of this study.
12:55:52 **A.** Okay.
12:55:54 **Q.** On the second paragraph under "Discussion" it says: "Because the main source of contamination in total joint replacement is wound infection via operating room air, we attempted to mimic perioperative contamination by inoculating the bacteria into the joint immediately after wound closure."
12:56:10 Did I read that correctly?
12:56:13 **A.** Yes. That's what they say.
12:56:13 **Q.** You disagree with that; don't you?
12:56:15 **A.** I do.
12:56:15 **Q.** Okay. So disagree with a study that you think is authoritative; correct?





12:56:18 **A.** Well the focus I had was on the infecting dose.
12:56:18 **Q.** Okay.
12:56:21 **A.** That's what I was trying to get at.
12:56:24 **Q.** Well this didn't really talk about infecting dose, this was more of, like, what occurs when the patien -- when the -- when the rabbit gets infected, and following the infection by doing MRI; correct?
12:56:32 MR. COREY GORDON: Object to the form of the question.
12:56:33 **A.** What --
12:56:34 **Q.** Correct; "yes" or "no"?
12:56:35 **A.** In other words, I'm trying to find any data that I could, at least in a brief survey, of what it takes to infect the joint, --
12:56:41 **Q.** Okay. So you like --
12:56:42 **A.** -- and this was one of the studies.
12:56:44 **Q.** So you like to take -- you like to take the data that supports your position --
12:56:46 **A.** No.
12:56:47 **Q.** -- and then disregard data that doesn't support your position; correct?
12:56:50 **A.** No, that's not true.
12:56:51 **Q.** So you think that --
12:56:52 **A.** I've already shown you studies where there





12:56:55 were data that I had, some clinical data, where it didn't support it, so you know that.
12:56:59 **Q.** But you disregard the -- the -- these authors here that did this study that said that the -- that -- that the main source of contamination in total joint replacement is wound infection via operating room.
12:57:12 You disregard that; correct?
12:57:13 **A.** I disagree with that. That had nothing related -- They didn't look at where the organisms came from here. They had them in the syringe and injected them.
12:57:22 **Q.** Okay. But that's why they injected them the way they did; correct?
12:57:26 MR. COREY GORDON: Object to the form of the question, also lack of foundation.
12:57:28 **Q.** I mean --
12:57:28 **A.** I don't know why they did what they did, but they do say that they -- they think it's airborne. I disagree with that.
12:57:34 **Q.** It says --
12:57:34 **A.** They injected animals, and that's the kind of dose that they used to get infection.
12:57:38 **Q.** "...we attempted to mimic perioperative contamination by inoculating the bacteria in the joint

12:57:42 immediately after wound closure."
12:57:44 Did I read that correctly?
12:57:44 **A.** Yes.
12:57:45 **Q.** And they did that because the main source of
12:57:47 contamination, according to them, in total re -- joint
12:57:51 replacement is wound infection via operating room air;
12:57:54 correct?
12:57:55 **A.** That's what they said.
12:57:56 MR. COREY GORDON: Object to the form of
12:57:58 the question, lack of foundation.
12:58:21 **Q.** Going to page 78.
12:58:23 **A.** Okay.
12:58:28 **Q.** Under the sheep model, --
12:58:30 **A.** Yeah.
12:58:31 **Q.** -- Williams D. L., --
12:58:33 **A.** Yeah.
12:58:33 **Q.** -- the Journal of Biomedical Materials;
12:58:36 correct?
12:58:36 **A.** Yes.
12:58:37 **Q.** They inoculated the sheep with only 10 CFU;
12:58:40 correct?
12:58:40 **A.** Yeah, on the membrane.
12:58:43 **Q.** Okay. And that's not that many CFU;
12:58:45 correct?
12:58:46 **A.** That's a low number.





12:58:47 **Q.** Okay. And in fact isn't it fair or accurate
12:58:54 that in this point in time you have absolutely no
12:58:58 opinion to the amount of CFUs required to cause a
12:59:03 periprosthetic joint infection?
12:59:05 **A.** What I would say is that I think -- I think
12:59:09 it's fewer organisms to cause a periprosthetic
12:59:16 infection than with a non-periprosthetic infection.
12:59:19 If you asked me to come up with a number, it's harder
12:59:22 to find that. You want me to pick a number and?
12:59:26 **Q.** I don't want you to guess.
12:59:27 **A.** Yeah.
12:59:27 **Q.** I mean, I'm looking at your last paragraph.
12:59:29 **A.** Yeah.
12:59:30 **Q.** I mean, you do say, "It is generally thought
12:59:32 that with a foreign body (joint prosthesis), the
12:59:36 infecting dose of bacteria is less than that for
12:59:39 surgeries in which no foreign device is placed";
12:59:41 correct?
12:59:42 **A.** And I stand by that.
12:59:42 **Q.** Okay. You just don't know what the
12:59:44 infecting dose is; correct?
12:59:45 **A.** That's true.
12:59:45 **Q.** But we could agree, based on some of the
12:59:48 rabbit models, that it could be as low as 17.
12:59:50 **A.** No, that's not true. In the experimental





12:59:53 model, yes, you can create an infection by injecting
12:59:56 organisms directly into the joint or injecting
13:00:00 organisms into the vein. That's not what surgeons do
13:00:02 when they're putting a prosthesis in. They don't take
13:00:05 a syringe of Staph, inject it directly into the joint
13:00:09 or put it into the IV.
13:00:11 **Q.** Can we agree at least that it's at least a
13:00:15 magnitude of 100 times less between a superficial and
13:00:18 a prosthetic?
13:00:19 **A.** I don't know -- I don't know what the number
13:00:21 is, so I've told you that. I think it's going to be
13:00:24 less. I don't know.
13:00:24 **Q.** How much less?
13:00:27 **A.** I don't know.
13:00:27 You asked me to, you know, come up with a
13:00:29 number, and then you say, well don't guess, because
13:00:32 there just aren't the data.
13:00:33 Now the other thing to tell you related to
13:00:35 -- You want to jump from here to people, which is
13:00:37 fine --
13:00:38 **Q.** I don't want to jump to people yet.
13:00:40 **A.** -- you know, but, you know, to infect a
13:00:44 rabbit by injecting it into the joint, I would say,
13:00:47 yes, it takes very few bacteria.
13:00:50 **Q.** Okay.





13:00:50 **A.** That's what I'll know from this study. Or
13:00:53 sheep, in this case.
13:00:54 **Q.** And as little --
13:00:55 When you're injecting as little as 17
13:00:57 bacteria.
13:00:58 **A.** They're very low numbers, yeah.
13:01:01 **Q.** But the rabbit study we showed 17 --
13:01:01 **A.** Yeah.
13:01:04 **Q.** -- bacteria based on the IV -- for 50
13:01:05 percent of the population from rabbits; --
13:01:07 **A.** Yeah.
13:01:07 **Q.** -- correct?
13:01:08 **A.** I think that's right.
13:01:09 Where was that where you're referring to?
13:01:11 **Q.** On the first one, the Southwood.
13:01:13 **A.** The Southwood. Okay.
13:01:20 Yeah.
13:01:20 **Q.** Okay?
13:01:20 **A.** Yeah.
13:01:21 **Q.** And that's for 50 percent of the population
13:01:24 to infect; correct?
13:01:25 **A.** Of animals, right.
13:01:28 **Q.** Okay. So that means 17 CFUs would infect 50
13:01:31 percent of the rabbits in that scenario.
13:01:32 **A.** If you inject them.

13:01:34 **Q.** If you inject them.
13:01:35 Which means that there is a percentage of
13:01:36 people that -- percentage of rabbits that require less
13:01:40 than --
13:01:40 **A.** Might be.
13:01:41 **Q.** -- 17 CFU --
13:01:42 **A.** Might be.
13:01:42 **Q.** -- to cause an infection.
13:01:43 **A.** Yeah.
13:01:44 **Q.** Okay.
13:01:51 (Interruption by the reporter.)
13:01:51 BY MR. ASSAAD:
13:01:53 **Q.** And in fact if you go back to Exhibit Number
13:01:56 8, you see that under Figure 2 that as little as one
13:02:12 CFU could cause an infection in the rabbits under the
13:02:20 medullary graph.
13:02:22 **A.** 1.3 times 10 to the something.
13:02:24 **Q.** No. I'm looking at the graph itself. You
13:02:26 see where -- You see where it says "Medullary (no
13:02:30 prosthesis)", it starts around 20?
13:02:32 **A.** Yeah.
13:02:32 **Q.** Okay. That means for anything below 20
13:02:35 times 10 to the X there was no infection; correct?
13:02:39 **A.** Yes.
13:02:39 **Q.** But with the medullary where there was a





13:02:41 prosthesis you agree that it almost starts at zero.
13:02:44 **A.** It's very low.
13:02:45 **Q.** Very low. Less than 17.
13:02:47 **A.** Yes.
13:02:47 MR. COREY GORDON: Object to the form of
13:02:47 the question.
13:02:49 **Q.** Okay. 17 CFUs was for the 50 percent;
13:02:51 correct?
13:02:53 **A.** That's what they found.
13:02:53 **Q.** Okay.
13:02:53 (Wenzel Exhibit 10 marked for
13:02:53 identification.)
13:02:53 BY MR. ASSAAD:
13:04:29 **Q.** What's been marked as Exhibit 10 are emails
13:04:31 between you and Dr. Darouiche that was provided to us.
13:04:35 This look like the email that you've had between him?
13:04:37 **A.** Yes.
13:04:38 **Q.** And I just want to talk about one thing.
13:04:41 During -- During --
13:04:42 You questioned him about this study in
13:04:45 formulating your opinions in this case; correct?
13:04:47 **A.** Yeah.
13:04:47 **Q.** Okay. And in fact one of your questions was
13:04:50 whether or not a forced-air warming device was used in
13:04:52 the operating room during his -- during the study in





13:04:57 which he compared biological load and surgical-site --
13:05:00 and periprosthetic joint infections; correct?
13:05:03 **A.** Yes.
13:05:05 **Q.** And you found out that all patients were
13:05:05 used -- were given a warming device; correct?
13:05:06 **A.** That's what he said.
13:05:08 **Q.** Okay. That's all I have.
13:05:18 What is the difference between a superficial
13:05:22 surgical-site infection and a periprosthetic joint
13:05:24 infection?
13:05:25 **A.** Well a deep infection would be that at the
13:05:28 fascia level or below.
13:05:29 **Q.** Is a deep joint infection different than a
13:05:33 periprosthetic joint infection?
13:05:33 **A.** I would classify them the same as deep
13:05:35 infection.
13:05:36 **Q.** Well you could have a deep infection but not
13:05:37 have -- but it doesn't reach the joint; correct?
13:05:40 **A.** Could possibly, yeah.
13:05:41 **Q.** Okay.
13:05:42 **A.** But by that time you're in trouble, yeah.
13:05:44 **Q.** You're in trouble, but there is a
13:05:45 distinction; correct?
13:05:46 **A.** There could be, yeah.
13:05:47 **Q.** Okay. I mean, there is technically a





13:05:49 superficial surgical-site infection; correct? Which
13:05:53 is --
13:05:53 **A.** There are superficial.
13:05:55 **Q.** -- pretty much the skin area and the first
13:05:56 couple layers, the first --
13:05:57 **A.** Yeah.
13:05:57 **Q.** Okay. Then you have a deep joint, which can
13:06:00 include the -- or --
13:06:03 So you could have a deep -- a deep
13:06:07 infection, right, which could include the joint or may
13:06:10 not include the joint; correct?
13:06:11 **A.** Yes.
13:06:11 **Q.** And then you have a periprosthetic joint
13:06:13 infection which definitely includes the joint;
13:06:14 correct?
13:06:15 **A.** That is the same.
13:06:16 **Q.** Okay.
13:06:17 **A.** I would use the same.
13:06:20 **Q.** You'd use the same?
13:06:20 **A.** Yeah.
13:06:20 **Q.** You've never seen it in the literature where
13:06:21 it's been distinguished?
13:06:23 **A.** No, I said I would -- I would say a
13:06:25 periprosthetic joint is a deep joint infection, yeah.
13:06:26 **Q.** Okay. But a deep joint infection may not

include the peripros --
**A.** May not.
**Q.** Okay.
(Interruption by the reporter.)
**Q.** A deep joint infection may not include a periprosthetic joint infection; correct?
**A.** Yes.
**Q.** Okay. And in fact you agree with me that you could have a periprosthetic joint infection and not have a superficial surgical-site infection.
**A.** Yes.
**Q.** Okay. And in fact you could have a periprosthetic joint infection and not have a -- a deep wound infection.
**A.** Yeah, I can't cite anything where I know that, yeah.
**Q.** And you agree that with respect to a periprosthetic joint infection, that the most likely time that a -- a patient obtained the bacteria that causes the periprosthetic joint infection was during the time that the patient was in surgery.
MR. COREY GORDON: Object to the form of the question.
**A.** Yeah, most people think that's the time when things happen.





**Q.** You don't disagree with that.
**A.** No.
**Q.** Okay. Now let's just assume that we're dealing with a -- a periprosthetic joint infection that is not also a superficial wound infection. You agree that the bacteria that causes the infection occurred perioperatively.
**A.** Yes, --
MR. COREY GORDON: Object to the form of the question.
**A.** -- I think so.
**Q.** As compared to someone having an untreated superficial wound infection that tunneled down to the joint.
**A.** I see what you're saying, yes.
**Q.** Okay. So you agree with that; correct?
**A.** Yeah.
**Q.** And what is your opinion on what is getting infect -- what -- where the bacteria is -- where the bacteria is when a periprosthetic joint infection -- And let me rephrase. That was a bad question. Strike that.
You agree it's possible that the implant itself could have bacteria on it before it's even placed in the joint.





**A.** Is it possible that --
**Q.** Yes.
**A.** -- that it could happen?
**Q.** Yes.
**A.** I can't cite a study but, you know, I never say "always" or "never."
**Q.** Well, for example, if a person handling the implant prior to placing it into the -- into the joint, if the person's hands are not sterile and has contaminants you might contaminate the implant; correct?
**A.** So in a hypothetical situation if somebody contaminates the implant, the implant is contaminated.
**Q.** Yes.
**A.** Yes.
**Q.** Okay. And, I mean, with everything, even instruments, we sterilize instruments because we don't want contaminated instruments to cause infection; correct?
**A.** That's right.
**Q.** There's been studies that sterilization of instruments reduces the incident of infection; correct?
**A.** I think so.
**Q.** I mean, otherwise -- I mean -- I mean,





that's just common knowledge; correct?
**A.** Yes.
**Q.** I mean in fact there's really no prospective study that washing hands reduces the incident of infection; is there?
**A.** I think there's lots of studies that show that.
**Q.** Prospective or retrospective?
**A.** Probably I would go back to Semmelweis.
**Q.** Okay.
(Interruption by the reporter.)
(Discussion off the stenographic record.)
**A.** Do you understand his studies?
**Q.** I know the study, but wasn't that retrospective?
**A.** He was there through the whole time.
(Discussion off the stenographic record.)
**Q.** But in any event, we agree that if devices that are used during a surgical procedure are contaminated, they may cause infections.
**A.** If you have a contaminated instrument, it's certainly possible that something might happen and the patient could get infected.
**Q.** And that -- that would be considered an exogenous source; correct?

13:11:12 **A.** It would be considered an exogenous source, but let's make sure that we have the terms down. If the -- If the instrument that you are saying in this hypothetical case actually was contaminated with the patient's own flora, then we have to have a little bit more strict definition.

13:11:31 **Q.** And I understand that. And that's why after usually the first incision they change the scalpel so they don't infect the wound with the patient's flora; correct?

13:11:40 MR. COREY GORDON: Object to the form of the question, assumes facts not in evidence.

13:11:43 **A.** As far as I know that's correct, yeah.

13:11:45 **Q.** Okay. I mean, you do understand that orthopedic surgeons and the hospital staff in an operating room have -- place procedures and techniques to reduce the risks of infection during an operating procedure.

13:12:02 **A.** Surgeons hate to have an infection.

13:12:05 **Q.** Okay.

13:12:06 **A.** They really never want to have one.

13:12:08 **Q.** And in fact are you aware that many surgeons, before they touch the implant, change their gloves?

13:12:12 **A.** Yes.





13:12:13 **Q.** Okay. Because they don't want to infect the implant; correct?

13:12:19 MR. COREY GORDON: Object to the form of the question.

13:12:21 **Q.** Because if you -- if bacteria gets on the implant, it may form biofilm and cause a serious periprosthetic joint infection; correct?

13:12:28 MR. COREY GORDON: Same objection.

13:12:29 **A.** What I would say about biofilm, biofilm is -- occurs after the organisms are onto the implant. So contaminated hands don't cause a biofilm. The organisms land on a site, there is a process under which quorum sensing occurs, and you know what I'm talking about. And with quorum sensing then the biofilm is formed. It's sort of like a broadcast email to the other organisms to start making biofilm.

13:13:01 **Q.** And I understand that.

My question was that the -- I'm not saying that the surgeon transfers biofilm. Listen to my question.

The surgeon changes his gloves because he doesn't want to contaminate the implant; correct?

13:13:14 **A.** I think that's correct.

13:13:16 **Q.** Okay. And the reason why you don't want to cause an im --





13:13:19 And the reason why he changes his gloves is because he doesn't want to place any bacteria on the implant; correct?

13:13:25 **A.** I think he wants to minimize any possibility.

13:13:28 **Q.** Okay. And then after the im --

And then the implant is placed, and that bacteria, at a later point in time, may cause biofilm, which would make it very difficult for the body to fight off.

13:13:38 **A.** In that scenario it could happen.

13:13:40 **Q.** Okay. And in fact they do all this to not infect the patient; correct?

13:13:46 **A.** Surgeons hate to have an infection.

13:13:47 **Q.** And have you yourself looked at an implant under an electron microscope?

13:13:49 **A.** No.

13:13:55 **Q.** Okay. Are you aware that an implant is not smooth and there are many crevices for bacteria to place themselves in?

13:13:57 **A.** Well I haven't looked at one, but it doesn't surprise me, but I haven't looked at one.

13:14:00 **Q.** Okay. And you understand that the reason why the body has a difficult time removing an infection or bacteria from an implant is because





13:14:05 there's very little vascularity to the implant.

13:14:06 **A.** It's the --

13:14:09 THE WITNESS: Go ahead. I'm sorry.

13:14:11 MR. COREY GORDON: No. Go ahead.

13:14:12 **A.** It's the low vascularity and the biofilm I think are a couple of key --

13:14:23 **Q.** Is there any vascularity to an implant?

13:14:25 **A.** None.

13:14:27 **Q.** Okay. So you would agree with me that once someone has an infected implant, giving the patient antibiotics without any type of vascularity is pretty much ineffective.

13:14:27 **A.** That's not true. There are people in Switzerland that have actually gone to drugs that penetrate the biofilm. Examples of such antibiotics include the fluoroquinolones and rifampin.

13:14:29 (Interruption by the reporter.)

13:14:31 THE WITNESS: Fluoroquinolones. Sorry. Fluoroquinolones and rifampin.

13:14:32 **A.** And they've been able to spare patients -- and I don't know totally what the follow-up is, so -- but 6 to 12 months later, without having to take the implant out. This is a hot area that people are trying to look at, because it's devastating to have the implant removed.

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13:15:25 **Q.** I understand. And -- And that's in --
13:15:29 And that's in Switzerland, you said?
13:15:31 **A.** Yeah.
13:15:31 **Q.** Okay. But in the United States are we using
13:15:33 those drugs yet?
13:15:34 **A.** We are.
13:15:35 **Q.** Okay. And you don't know how effective they
13:15:37 are.
13:15:38 **A.** They look effective, and so when we're
13:15:40 treating these infections, we're -- you know, trying
13:15:42 to cool things down if it's already infected, we will
13:15:46 often use a drug that penetrates biofilm; one of those
13:15:49 two drugs, plus other antibiotics. So that's going
13:15:53 on.
13:15:54 Are there patients in this country where you
13:15:57 can't, for some reason, maybe a very old person who
13:16:01 couldn't tolerate a surgery, as an example. Are they
13:16:05 getting these drugs? Yes, they are, to try to spare
13:16:08 them to have a surgery. With some success.
13:16:10 **Q.** Are these drugs done intravenously, or is it
13:16:13 direc -- are they inoculated directly with the
13:16:15 antibiotic right onto the implant?
13:16:17 **A.** Actually both are bio-available orally.
13:16:20 **Q.** Okay.
13:16:20 **A.** The fluoroquinolones and rifampin.





13:16:23 **Q.** But usually --
13:16:26 You agree with me that most like -- the
13:16:26 standard of care and the most predominant treatment
13:16:29 for a periprosthetic joint infection is a two-stage
13:16:32 revision.
13:16:33 **A.** Usually that's --
13:16:34 MR. COREY GORDON: Object to the form of
13:16:34 the question, --
13:16:35 THE WITNESS: Oh, okay. Sorry.
13:16:36 MR. COREY GORDON: -- lack of foundation.
13:16:38 **A.** I don't know if --
13:16:39 I think that is a standard. I don't know
13:16:41 across the country how many people are doing that, but
13:16:44 it's often happened --
13:16:44 **Q.** Okay.
13:16:45 **A.** -- that way.
13:16:53 **Q.** Now are you familiar with the preparation a
13:16:57 patient goes through with respect to skin prep and
13:17:06 draping for a total knee or total hip arthroplasty?
13:17:10 MR. COREY GORDON: Object to the form of
13:17:11 the question.
13:17:11 **A.** I'm not a sur --
13:17:13 MR. ASSAAD: Basis?
13:17:13 MR. COREY GORDON: A, it's compound; B,
13:17:16 you're -- it's a one-size-fits-all question. So if





13:17:20 he -- He can't answer a compound question, and he
13:17:22 can't answer a one-size-fits-all question.
13:17:24 MR. ASSAAD: I'll -- Fair enough.
13:17:25 BY MR. ASSAAD:
13:17:26 **Q.** Have you ever seen a total hip surgery?
13:17:30 **A.** I haven't actually, no.
13:17:31 **Q.** Have you seen a total knee surgery?
13:17:33 **A.** No.
13:17:34 **Q.** Have you seen how a patient's prepped during
13:17:35 those types of surgeries?
13:17:37 **A.** Only the, you know, the description that Dr.
13:17:40 Mont gave at Science Day.
13:17:42 **Q.** Okay.
13:17:42 **A.** Very elaborate preparation.
13:17:45 **Q.** Okay. But you're aware of the types of skin
13:17:48 preps that are used on these patients; correct?
13:17:50 **A.** You're talking about chlorhexidine alcohol?
13:17:52 **Q.** Yes.
13:17:52 **A.** Yes.
13:17:53 **Q.** Okay. And there's other types of -- of skin
13:17:55 preps as well; correct?
13:17:56 **A.** Some people use iodophors.
13:17:56 **Q.** With alcohol?
13:18:02 (Interruption by the reporter.)
13:18:03 **A.** Today, Iodophor. And I think the tendency





13:18:06 is today if you're going to use an iodophor to use one
13:18:09 with an alcohol.
13:18:10 **Q.** Okay. And in fact do you agree with me that
13:18:13 the CDC has stated that there's really no difference
13:18:15 between the iodophor with alcohol and the chlorhex
13:18:18 with alcohol?
13:18:19 **A.** I'm not sure that's how they phrased it, but
13:18:21 they recommend a prep with an alcohol.
13:18:24 **Q.** Okay. Whether or not it's chlorhex or
13:18:28 iodophor.
13:18:29 **A.** Yeah. I think they opened the door to have
13:18:31 io -- iodophor with alcohol --
13:18:31 **Q.** Okay.
13:18:34 **A.** -- in their recommendations.
13:18:36 **Q.** Do you -- Do you agree with the CDC
13:18:38 recommendation?
13:18:39 **A.** Yeah. I actually think that -- that there's
13:18:43 probably advantages of chlorhexidine alcohol over
13:18:46 iodine alcohol, and that's based on the two MIMO
13:18:50 studies that I cite.
13:18:51 **Q.** And you actually reviewed the CDC
13:18:56 prevention -- Guideline For the Prevention of
13:18:57 Surgical-Site Infection in preparation of your report;
13:18:59 correct?
13:19:00 **A.** Yes.

13:19:00 **Q.** It's actually on Exhibit 2; correct?
13:19:05 **A.** Do you want me to go to that?
13:19:06 **Q.** Well it's on your -- on your list.
13:19:08 **A.** Okay. Yeah. Yeah.
13:19:46 **Q.** What is the mechanism -- Well, strike that.
13:19:49 Skin flora is on the skin and may be in the
13:19:55 pores, correct, either the sweat glands or the
13:19:58 follicles; correct?
13:19:58 **A.** Yes.
13:19:59 **Q.** Does it go any deeper than that?
13:20:01 **A.** Normally, no.
13:20:03 **Q.** Okay. So we have the -- we have flora
13:20:04 that's on the skin and in the sweat glands and -- and
13:20:07 the follicle -- the hair follicles and nowhere else.
13:20:10 **A.** And sebaceous glands.
13:20:12 **Q.** What are the sebaceous glands?
13:20:13 **A.** What are they?
13:20:14 **Q.** Yeah.
13:20:14 **A.** They're the glands that are primarily found
13:20:17 that secrete -- they're also below the dermis. They
13:20:22 secrete -- I have a picture of it, I think.
13:20:25 **Q.** I believe that's where we're going right
13:20:27 now.
13:20:27 **A.** Yeah. And --
13:20:30 Do you want to wait and go to the picture?





13:20:42 MR. GOSS: 23?
13:20:42 **Q.** 23.
13:20:46 **A.** Yeah.
13:20:47 **Q.** Okay.
13:20:48 **A.** So do you want me to explain what sebaceous
13:20:50 glands are?
13:20:50 **Q.** Well I asked --
13:20:51 So they're -- they're between the skin
13:20:53 surface and the fat; correct?
13:20:58 **A.** Yeah. They're below the -- the dermis
13:21:02 there, the -- the skin surface, right.
13:21:04 **Q.** And you're saying that bac -- that flora
13:21:05 could be in the sebaceous glands?
13:21:07 **A.** There's no question about it.
13:21:09 Propionibacterium acnes has been recognized to be
13:21:12 there.
13:21:12 **Q.** And that's P. acnes?
13:21:14 **A.** P. acnes.
13:21:15 **Q.** Okay. But that's mostly found on the
13:21:17 shoulders; correct?
13:21:18 **A.** Shoulder and back.
13:21:18 **Q.** And back, but not -- it's not -- it's not
13:21:20 normally found in the knee or hip; correct?
13:21:22 **A.** It's very unusual to find --
13:21:22 **Q.** Okay.





13:21:23 **A.** -- infections with Propionibacterium --
13:21:23 **Q.** So would you agree with me that --
13:21:26 **A.** -- otherwise.
13:21:28 **Q.** -- that if a patient had P. acnes infection
13:21:30 that it probably did not come from the patient, or if
13:21:32 it did, it was through some sort of direct contact --
13:21:32 MR. COREY GORDON: Object --
13:21:36 **Q.** -- of a hip or knee?
13:21:37 **A.** Oh. Oh.
13:21:37 MR. COREY GORDON: Object to the form of
13:21:38 the question.
13:21:38 **A.** No. I mean, it's not -- I think I've cited
13:21:41 occasionally it can happen in either hips or knees, I
13:21:45 forgot where.
13:21:45 **Q.** I think articles on shoulder surgery.
13:21:47 **A.** Pardon me?
13:21:48 **Q.** It was shoulder surgery that you were citing
13:21:51 it to.
13:21:51 **A.** Yeah, but also if you look at Tande and
13:21:53 Patel, I think I found 1 percent.
13:21:54 **Q.** How many percent?
13:21:55 **A.** One percent. So it's very low. In -- In
13:21:58 either hips or knees, I don't remember which cite I
13:22:00 had.
13:22:00 **Q.** But your --





13:22:01 But that could have come from -- I mean that
13:22:05 -- there was no microbiologic study done in that case
13:22:07 in which you know it came from the patient, it could
13:22:09 have come from one of the staff members by direct
13:22:12 contact.
13:22:12 **A.** There are no --
13:22:13 Not that I'm aware of any microbiologic
13:22:17 studies to confirm that the same one came there. But,
13:22:20 you know, we have sebaceous glands primarily in this
13:22:23 area [indicating], but they're not zero other places
13:22:25 of...
13:22:26 **Q.** I understand that. But if someone has P.
13:22:29 acnes infection in the hip or knee, --
13:22:30 **A.** Yeah.
13:22:31 **Q.** -- I mean it's very unlikely that it came
13:22:33 from them.
13:22:34 **A.** I don't know if it's unlikely.
13:22:35 **Q.** So you don't know one way or the other; do
13:22:37 you?
13:22:37 **A.** That's right.
13:22:37 **Q.** Okay. You just don't know.
13:22:38 **A.** I don't know.
13:22:39 **Q.** Okay. So -- And just roughly how far does
13:22:48 -- is the sebaceous gland and the hair follicle or the
13:22:51 sweat gland underneath the skin surface?

13:22:53 **A.** I don't know.
13:22:54 **Q.** A millimeter?
13:22:55 **A.** I don't know. Never seen any data on that.
13:22:58 I'm not sure.
13:22:59 **Q.** You don't know how thick the skin is?
13:23:01 **A.** No. Don't know.
13:23:04 **Q.** Okay. You've never --
13:23:08 **A.** Don't remember looking at it.
13:23:09 **Q.** -- never done -- in medical school did -- on
13:23:12 a cadaver and cut through the skin?
13:23:15 **A.** I did -- I did do that, yeah.
13:23:15 **Q.** Okay.
13:23:16 **A.** Wasn't very far, but I don't know.
13:23:17 **Q.** I mean, are we talking two inches?
13:23:19 **A.** Probably not two inches. Less.
13:23:21 **Q.** An inch?
13:23:21 **A.** I don't know. I already --
13:23:21 **Q.** So you don't know?
13:23:22 **A.** -- told you I don't know.
13:23:24 **Q.** Okay. All right.
13:23:24 How far is it between the -- the sweat
13:23:34 gland, which I think is the lowest, and a knee joint?
13:23:41 **A.** I don't know.
13:23:42 **Q.** How far is it between a sweat gland --
13:23:44 Well you agree the sweat gland look likes





13:23:47 it's the lowest in this picture here?
13:23:49 **A.** Well in the picture it looks like it's at
13:23:51 the same level as the sebaceous glands roughly, so.
13:23:54 **Q.** Okay. Well let's just say whatever is
13:23:56 lowest, how far do you think the bacteria is that's on
13:23:59 a patient's skin or in the glands or -- from a knee
13:24:04 joint?
13:24:06 **A.** I don't know how -- what the distance is in
13:24:08 millimeters or not.
13:24:09 **Q.** Okay. Well you agree that there's no -- I
13:24:13 mean, if a person is not -- doesn't have sepsis or an
13:24:15 infection there's no bacteria in the fat; correct?
13:24:22 **A.** I think that's true.
13:24:23 **Q.** Okay. And --
13:24:24 **A.** No. No. Well in the fat, yeah. I think
13:24:27 that's true.
13:24:27 **Q.** And you agree with me there'd be no bacteria
13:24:29 in the muscle if a person doesn't have an infection.
13:24:29 **A.** Yes.
13:24:32 **Q.** Ongoing infection; correct?
13:24:33 **A.** If they don't have an infection?
13:24:33 **Q.** Ongoing infection, yeah.
13:24:33 **A.** Yes.
13:24:33 **Q.** Okay. And you agree with me that the --
13:24:37 (Interruption by the reporter.)





13:24:37 **Q.** And you agree with me that there's no
13:24:40 bacteria in the blood if the person doesn't have some
13:24:41 sort of blood infection.
13:24:42 **A.** By definition.
13:24:44 **Q.** Okay. Because in fact if someone had sepsis
13:24:47 or a blood infection it probably wouldn't be a good
13:24:50 time to do elective surgery; correct?
13:24:52 MR. COREY GORDON: Object --
13:24:52 **A.** To do what?
13:24:53 **Q.** Elective surgery.
13:24:54 MR. COREY GORDON: Object to the form of
13:24:55 the question, also lack of foundation.
13:24:56 **A.** I don't think I understand the question I
13:24:57 guess.
13:24:57 **Q.** Well if someone had an infection, an ongoing
13:24:59 infection, --
13:24:59 **A.** Oh.
13:25:00 **Q.** -- it wouldn't be -- it wouldn't be proper
13:25:01 to do --
13:25:01 **A.** Oh, I see.
13:25:04 **Q.** -- elective surgery.
13:25:04 **A.** I'm sorry. Didn't understand the que --
13:25:05 Yeah. I try to --
13:25:05 MR. COREY GORDON: Wait until he finishes.
13:25:07 THE REPORTER: Yes, please.





13:25:08 **A.** So to answer the question. One of the
13:25:11 things that you want to do for any surgery that's
13:25:15 elective is not to have any source of infection
13:25:18 anywhere.
13:25:27 **Q.** Okay. So you mentioned that there is the --
13:25:29 the chlorhex with alcohol and the io -- iophorm [ph]?
13:25:34 **A.** Iodophor.
13:25:36 **Q.** Iodophor with alcohol.
13:25:37 What percentage of the bacteria do those
13:25:39 prep solutions kill?
13:25:42 **A.** I don't think I know the answer to that, but
13:25:43 a high proportion.
13:25:44 **Q.** 99.9?
13:25:46 **A.** I don't know.
13:25:47 **Q.** You don't know?
13:25:48 **A.** Might be, but I don't know. I can't cite
13:25:51 any -- And if I answer you I want to try to cite the
13:25:54 reference, that's what I'm saying.
13:25:54 **Q.** Okay. So sitting here today, you don't
13:25:56 know.
13:25:56 **A.** No.
13:25:57 **Q.** Okay. And does it kill the bacteria that's
13:25:59 in the -- the subacaneous -- or the sebaceous gland?
13:26:06 **A.** No, it doesn't.
13:26:07 **Q.** Okay. What about the sweat glands?

13:26:08 **A.** No.
13:26:09 **Q.** What about the hair follicles?
13:26:10 **A.** No.
13:26:11 **Q.** Okay. So is it your opinion that the most likely cause of a periprosthetic joint infection is that the bacteria is most likely coming from the -- either the sweat gland, the sebaceous gland or the hair follicle?
13:26:32 **A.** That's too general a statement. For example, the reason I say that, there are people who've done things like skin preps. You first -- You know, Daeschlein did a study just to look -- from Germany -- using an alcohol skin prep and he still finds bacteria in about 8 to 10 percent of people after the prep. And then during the surgery you can find more.
13:26:59 If I go back to the people who've looked at, let's say, shoulder surgery, first of all, you know, you saw from my report that I -- one study that was very large showed 21 percent of infections of the shoulder due to P. acnes. That's the implant. If you look at just rotator cuff we're talking 50, 55 percent of infections, rotator cuff, are P. acnes. If you look at spine repair for scoliosis, again about 50 percent are P. acnes. That's where the organism





13:27:36 lives.
13:27:37 Now if you -- peo -- I've -- I've quoted Sethi and Matsen and the -- a Japanese study that showed the organisms are there at the time of the incision, before the -- after the prep, before the incision. And Shiono's study with the spine and the back where they're repairing scoliosis. So 36 percent of the time after the prep they can find P. acnes. And then when they go in and actually look at the lamina, immediately exposing the lamina, it's already colonized in something like 25 or 35 percent.
13:28:19 So to me that comes back to the microbiome, back to the fact that we don't have a perfect skin disinfectant or antiseptic, rather, and the organism's there.
13:28:34 **Q.** For P. acne.
13:28:34 **A.** Yeah. That's the marker organism because it's hard to track, you know, a Staph epi, for example.
13:28:41 **Q.** Is there Staph epi in the hair follicles?
13:28:43 **A.** Not that I'm aware of, no.
13:28:44 **Q.** Is there Staph epi in the -- in the glands?
13:28:47 **A.** Don't think so.
13:28:48 **Q.** What about Staph aureus?
13:28:49 **A.** No.





13:28:50 **Q.** What type of bacteria are in the glands?
13:28:51 **A.** The one that I've talked about is P. acnes.
13:28:54 **Q.** Okay. So that's the only bacteria that you're aware of --
13:28:56 **A.** That's the only one that I'm aware of --
13:28:56 **Q.** Okay.
13:28:58 **A.** -- and it links to the --
13:29:00 **Q.** So would it be fair to say that if a person has a Staph aureus or a Staph epidermis or -- Strike that -- if a person doesn't have a P. acnes infection, that the most likely -- according to the most likely source of the infection would be from the skin and not the glands.
13:29:24 **A.** For Staph aureus, the source --
13:29:26 **Q.** Staph aureus, MRSA, Staph epidermidis. Everything besides P. acnes.
13:29:31 **A.** Yeah. Let me just refine a little bit.
13:29:33 So carriers of Staph in the nose are, you know, always at higher risk than non-carriers, two to three times fold for Staph infection. It turns out if you're a carrier in the nasal microbiome, you have a high chance of carrying it somewhere else, perineum, groin, axilla, as you know.
13:29:59 **Q.** And I'm just talk --
13:29:59 We're going to get there, and I promise you





13:30:00 we're going to get to the nose issue.
13:30:02 I'm talking about where we're looking at the skin here --
13:30:04 **A.** Yep.
13:30:05 **Q.** -- on page -- on -- I'm just trying to determine what's the most likely source of the different type of bacteria.
13:30:12 So if you look at page 23, okay?
13:30:19 **A.** Yeah. I've got it.
13:30:26 **Q.** The only bacteria that you are aware of that would reside in the glands or the hair follicles is P. acnes; correct?
13:30:33 **A.** That's all I know.
13:30:34 **Q.** Okay. So if a patient was infected with anything besides P. acnes, the most likely source, from looking at this picture, Figure 4 on page 23, would be the skin surface; correct?
13:30:46 **A.** That's my current hypothesis. I haven't seen a lot of studies. I can tell you about the sternal surgery for CABG with or without.
13:30:56 **Q.** Well I just want to know what your opinion is.
13:30:58 **A.** Yeah.
13:30:59 **Q.** I don't need to know your studies.
13:31:00 **A.** No. I'm just trying to say why I say what I

13:31:02 do or don't say what I do.
13:31:04 **Q.** So -- So my understanding is is that the
13:31:19 skin prep, such as the chlorhex with alcohol or the
13:31:24 other skin prep, would be able to reach the -- all the
13:31:30 bacteria that's on the skin part of the patient's
13:31:34 flora except for P. acnes; correct?
13:31:36 **A.** No, that's not true. They're ineffect --
13:31:39 They could reach the area.
13:31:40 **Q.** That was my question. They could reach it.
13:31:42 **A.** But they don't -- they're not effective in
13:31:45 eradicating all the flora there.
13:31:47 **Q.** That wasn't my question. I said they could
13:31:47 reach it.
13:31:47 **A.** Yeah.
13:31:47 **Q.** Correct?
13:31:47 They can't reach P. acnes because it's
13:31:56 underneath --
13:31:56 (Interruption by the reporter.)
13:31:56 **Q.** They can't reach P. acnes because it's below
13:31:59 the skin; correct? The -- The skin prep.
13:32:01 **A.** The currently used antiseptics don't
13:32:03 reach --
13:32:03 **Q.** Okay.
13:32:05 **A.** -- down into the sebaceous glands.
13:32:08 **Q.** Okay. But they could reach the skin





13:32:10 surface; correct?
13:32:10 **A.** They reach the surface. It's put on the
13:32:12 surface.
13:32:13 **Q.** Okay. And therefore the question is how
13:32:16 much of the bacteria do they eradicate, the
13:32:19 effectiveness of the skin prep; correct?
13:32:22 **A.** So say it again to make sure I got you.
13:32:25 **Q.** It reaches all the bacteria on the skin
13:32:31 surface, the skin prep, the issue is what percentage
13:32:35 of the bacteria it kills.
13:32:38 **A.** It's better to go back to the Darouiche
13:32:44 study to say that if you start with a -- you know, an
13:32:48 iodophor and compare it to chlorhexidine alcohol,
13:32:52 chlorhexidine alcohol is a better, more effective skin
13:32:55 prep than iodophor, reducing all surgical-site
13:33:02 infections by 40 percent. Follow-up study with Tuul
13:33:06 -- with Tuuli, thirt -- 45 percent, so it's very
13:33:10 consistent.
13:33:12 **Q.** And you would agree with me that all those
13:33:14 studies you're referring to are looking at superficial
13:33:17 wound infections.
13:33:18 **A.** Well --
13:33:20 **Q.** "Yes" or "no"?
13:33:21 **A.** I'm trying to think whether there were any
13:33:23 deep infections in those. I think Darouiche had some





13:33:27 deep infections. I don't --
13:33:28 **Q.** Which article are you --
13:33:30 **A.** -- I think --
13:33:30 Yeah. I thought that the Darouiche study on
13:33:36 -- his first study that I've quoted here on -- Let me
13:33:41 see if I can find the date. Comparing -- So I think
13:33:46 it's -- Well, let me just not guess. (Witness
13:33:46 reviewing exhibit.)
13:33:53 Wait. That'll be... So, you know, it's a
13:33:59 New England Journal paper. Oh, I'm sorry. December
13:34:05 2010 *New England Journal of Medicine*.
13:34:08 **Q.** And can you point me to the page you're
13:34:10 referring to?
13:34:12 **A.** I just remembered, so let me try to find the
13:34:14 page I'm referring to.
13:34:15 MR. COREY GORDON: In his report, or in the
13:34:17 article?
13:34:17 MR. ASSAAD: In his report.
13:34:19 **A.** Yeah, it's in my report. Okay.
13:34:22 So it'll be probably in the microbiome
13:34:30 section.
13:34:30 **Q.** Would it be page 25?
13:34:32 **A.** Let's look. (Witness reviewing exhibit.)
13:34:41 Yes. And I thought he talked about both.
13:34:51 My recollection he talks about some deep as well as





13:34:54 superficial.
13:34:57 **Q.** Are you aware that the surgeries that he
13:34:59 looked at were colorectal, small intestinal,
13:35:06 gastroesophageal, biliary, thoratic, gynecologic or
13:35:11 urolo -- urologic operations?
13:35:12 **A.** Yes.
13:35:13 **Q.** None of them had to do with total hip or --
13:35:13 **A.** That's --
13:35:15 **Q.** -- total knee?
13:35:15 **A.** -- true.
13:35:16 **Q.** None of them had to do with implants;
13:35:18 correct?
13:35:18 MR. COREY GORDON: Wait. Wait until he
13:35:18 asks his --
13:35:20 **A.** That's true.
13:35:20 **Q.** Okay. So can you -- can you identify me
13:35:24 today a study that shows that using a chlorhex with
13:35:32 alcohol reduces the incident of a periprosthetic joint
13:35:37 infection?
13:35:44 **A.** I don't think a study's been done just on
13:35:46 the joints. I'm trying to remember.
13:35:48 **Q.** So sitting here today there is no evidence
13:35:51 that a skin prep such as chlorhex with alcohol reduces
13:36:05 the incident of surgical -- of periprosthetic joint
13:36:10 infections; correct?

13:36:10 **A.** Well I would say there's no study out there, but if you take skin, the -- what we're really talking about is controlling the microbiome. And if you said to me today, I've got to get a hip replacement, I would tell you chlorhexidine alcohol, just as Dr. Reed did in his study, after awhile.

13:37:35 **Q.** You would agree with me that if -- if a -- Strike that.

If the bacteria comes from the patient's skin -- Let's take out P. acnes, okay? We could agree that P. acnes is a very unlikely cause of a infection for a total hip or total knee arthroplasty; correct?

13:38:19 **A.** Yes.

13:38:19 **Q.** Okay. Let's just assume all my questions is excluding P. acnes when I talk about bacteria going forward. Correct? Do you understand that?

13:38:27 **A.** If you want to make an assumption, yes.

13:38:30 **Q.** Yes. How does the bacteria get from the skin to the periprosthetic joint to cause an infection during the operation? If you know.

13:38:55 **A.** Well I have to go back to P. acnes, because it's the only study that shows that it's already there at the time of the incision, so it -- it's there. The other study I'd point to would be Tammelin's study of CABGs and Staph epi where he tried to do





13:39:14 fingerprinting to say if I look at the air, if I look at the surgeons and if I culture the patient's legs where the graft is for the CABG, or if I culture the sternum, he could find the only match that -- with any high numbers in the sternum for Staph epi. These are heart studies, but it comes back to what I've said earlier. If you have an organism, a marker organism and you can follow it, so he's able to do a fingerprint on those Staph epi on the sternum. I think I --

13:39:47 **Q.** Well I'm asking --

I mean, my understanding is, and it's a very limited understanding, that bacteria either need to be transferred by direct contact or they can be aerosolized. They don't have legs; correct? They don't move.

13:39:59 **A.** They can move, on the surface.

13:40:00 **Q.** How do they move?

13:40:02 **A.** I don't know how they move, but, you know, they're -- if there -- if there is an incision made across a group of bacteria, then why would you not think that they're actually going to fall into the wound? That's a hypothesis that I have --

13:40:18 **Q.** Is there any evidence --

13:40:19 **A.** -- but nobody -- nobody knows exactly how





13:40:21 they get from the flora to the wound. And I've said that in my report.

13:40:28 **Q.** Okay. So you have no opinion of how the bacteria get from the flora, patient's flora into the wound; correct?

13:40:36 **A.** Not in detail. I just know that they're already present at the time of the incision.

13:40:41 **Q.** Now do they jump from the patient's skin right into the -- into the joint, or would they go through the fascia and the mu -- and the muscle?

13:40:51 **A.** I don't know.

13:40:52 **Q.** Okay.

13:40:52 MR. COREY GORDON: Wait for him to --

13:40:54 THE WITNESS: I'm sorry.

13:40:54 MR. COREY GORDON: You gotta wait for him to finish the question.

13:40:56 THE WITNESS: Yeah. Apologize.

13:40:57 **Q.** Okay. So --

13:40:58 And you're aware that in many total hip and total knee arthroplasties, if not all, that patients are given a prophylactic dose of antibiotics.

13:41:12 **A.** Patients are given antibiotics, yes, preoperatively, perioperatively.

13:41:17 **Q.** Perioperatively. Actually before even incision.





13:41:19 **A.** Yes.

13:41:20 **Q.** Okay. And in fact that has shown to reduce the incident of superficial wound infection for total hip and total knee arthroplasty; correct?

13:41:33 **A.** More than that. I mean, if I go back to Lidwell's study, he -- when he looked at the patients who had perioperative antibiotics, their deep-joint infection rate was four times greater in the group that didn't have antibiotics.

13:41:50 MR. COREY GORDON: You said "greater."

13:41:53 THE WITNESS: I'm sorry.

13:41:54 **A.** The people who didn't get perioperative antibiotics had a four times risk of the prosthetic joint infections compared to the ones who did.

13:42:05 **Q.** So we agree that perioperative antibiotics decreases the risk of periprosthetic joint infections?

13:42:09 **A.** Yes.

13:42:10 **Q.** Okay. You do agree with me that the bacteria has to get to the -- to the joint area to cause a periprosthetic joint infection perioperatively; correct?

13:43:30 **A.** Bacteria are necessary, not sufficient, yes.

13:43:33 **Q.** Okay. And when we say "get to the joint area," we're getting to the prosthesis during the total hip or total knee arthroplasty; correct?

MR. COREY GORDON: Object to the form of the question.

**A.** I don't know exactly, you know, does it start above and then get moved to the joint, but that could happen, yeah.

**Q.** But for the biofilm to form it has to be in the prosthesis.

**A.** Yeah, it has to be on a foreign body. Well I think in --

**Q.** Most likely.

**A.** I think it's more likely, you know. In some chronic wounds they've shown biofilm. You probably know that.

**Q.** But with respect to total hip and total knee --

**A.** Yeah.

**Q.** -- the bacteria has to get to the prosthesis to form biofilm; correct?

**A.** I think that's right.

**Q.** Okay. So during the operation it's your opinion that a bacteria on the patient's skin gets to the prosthesis at some point in time to cause an infection -- to cause a periprosthetic joint infection.

MR. COREY GORDON: Object to the form of





the question.

**A.** So I think the source of al -- of almost all infections, including periprosthetic joint infections are the patient's flora, and again the skin would be the site primarily.

And I'm not sure that I understood the complex question.

**Q.** Well the bacteria that's on the patient's flora has to reach the -- the --

**A.** Has to get to the area --

**Q.** -- the prosthesis --

**A.** I'm sorry.

**Q.** -- has to get to the prosthesis during the operation.

**A.** Yes.

**Q.** Okay. Now when we talk about where the bacteria's coming from, are you talking about the skin where there -- it's been prepped and where the surgical site is, or are we talking about the fa -- the bacteria that's on the face of the patient that's underneath the drape?

**A.** I think, my -- my feeling today, is that it's primarily in the skin near the incision, and again the P. acnes studies would actually demonstrate that.





**Q.** Okay. Now with respect to people that are carriers for MRSA or MSSA in their nose, okay, the --

What's the correct word? What is the correct word for that?

**A.** You talking about a nasal?

**Q.** Yeah.

MR. COREY GORDON: Nares?

**A.** Nares?

**Q.** Yeah, the nares.

And you've talked about that in your report; correct?

**A.** Yeah.

**Q.** They're carriers; correct?

You're not offering the opinion that the bacteria in the nose is actually reaching the surgical site and the prosthesis and causing an infection; are you?

MR. COREY GORDON: Object to the form of the question.

**A.** What I think happens is that if you're a carrier in the nose you're frequently a carrier elsewhere on the body; it can be in the hands, as shown by Reagan, et al. If you want to look at Mermel and colleagues, it's carried in the groin and the perineum and axilla as well.





So if you look at all the people who are carriers of Staph, the most sensitive spot is going to be in the nose. We also know that there are carriers of, you mentioned MRSA, 15, 20 percent carry it only in the throat. And again I think that the nose is a marker for the increased likelihood of carriage in other places of the body.

**Q.** What's the likelihood that if you have MRSA or MSSA it's going to be on your knee?

**A.** The knee? I don't known. I haven't seen data.

**Q.** There's no evidence that -- that the fact that you're positive in your nose or even throat, means that you have MSSA or MRSA on your knee; correct?

**A.** No. But if it's the groin and you're talking about hip, for example, or a knee, is it possible? Could it happen? I don't -- can't cite a paper.

**Q.** But the groin is isolated during the surgery; correct?

**A.** It is isolated. I don't know how effective that is.

**Q.** Okay. Do you know what -- whether or not the drapes are permeable or impermeable in an

operating room?
**A.** No, I don't. I haven't looked at that.
**Q.** Okay. But you're not saying, just so I understand you, that if you have MRSA in the nose or MSSA in the nose, that as the patient breathes out that bacteria is coming out of your nose and infecting the prosthesis.
**A.** I don't know how if --
Let's say, imagine in a scenario that we're just making up to have the discussion, it's a carrier only in the nose. How it gets from the nose to the wound, I don't know completely. Is it possible that that could happen? Maybe. I don't know. There are no studies that show the organism in the nose can't move, can't be blown out.
**Q.** Okay. You do understand that in a total hip or total knee arthroplasty there is a huge drape that goes three feet above -- two to three feet above the patient; correct?
**A.** Yes.
**Q.** Okay. That separates the head of the patient --
**A.** That's right.
**Q.** -- from where the surgical site is; correct?
**A.** Yes. Sorry.





**Q.** And you agree with me that --
So are you saying that it's possible that the bacteria could come out of the nose and over the drape or around the drape and into the surgical site?
**A.** I don't know.
**Q.** Okay.
**A.** I mean, I... I know that people who have colds certainly disperse when they sneeze or cough or something, with Staph.
**Q.** But if the ventilation is doing what it's supposed to be doing, it would push the bacteria down; correct?
**A.** I think so.
**Q.** Okay. Unless there was something else out there that was causing the bacteria to go up; correct?
**A.** I think so.
MR. ASSAAD: Let's take a break.
THE REPORTER: Off the record, please.
(Recess taken from 1:50 to 2:05 p.m.)
THE WITNESS: Can I make just a -- you asked -- said earlier you didn't mind, Mr. Assaad, if I made changes, and just on break looked up the microbiome of the sebaceous glands, and in fact I can point to a reference for you, General Clinical Micro 1984, Leeming. And in addition to P. acnes,





Propionibacterium, both Staphylococcus, they didn't differentiate epi and aureus in the brief summ --
(Interruption by the reporter.)
THE WITNESS: -- epi from aureus, and also Pityrosporum. So I want to add that to my statement, and thank you for letting me amend.
BY MR. ASSAAD:
**Q.** Do you know how prevalent the Staph --
**A.** No. I have to do a lot more looking at it, but --
THE WITNESS: I'm sorry.
MR. COREY GORDON: Let him --
**Q.** So sitting here today, you don't know, like, what percentage or -- or where in the human biome they did the sampling.
**A.** They -- They sampled the sebaceous glands.
**Q.** But where?
**A.** I don't know.
**Q.** Could it have been on the shoulder or back?
**A.** Well you're asking me questions I don't know, --
**Q.** Okay.
**A.** -- but I gave you a reference and wanted to clear up the fact that Staphylococci can live there.
**Q.** What's the name of the reference?





**A.** General Clinical Micro, 1984, Lemming, L-E-M-M-I-N-G. I don't have the first initial.
**Q.** Lemming, L-E-M-M-I-N-G?
**A.** Yeah.
**Q.** Okay. Do you know who doctor --
MR. GOSS: It's actually L-E-E-M-I-N-G.
THE WITNESS: Oh, I'm sorry. Did I get that wrong?
**Q.** And you just looked that up where?
**A.** Yeah. Just now.
**Q.** On your phone?
**A.** I used his phone.
**Q.** Okay. You're pointing to Peter Goss?
**A.** Yes, Peter Goss.
**Q.** Did he provide the article to you?
**A.** He did.
**Q.** Okay. So you didn't look it up, he just gave --
**A.** I did. We were both looking things up just to check.
**Q.** Well who pulled up the article; was it you --
**A.** He did.
**Q.** -- or Peter Goss?
**A.** He did. Peter did.

14:07:01 **Q.** Okay. So my understanding is that while I'm
14:07:05 asking you questions Peter Goss is doing some research
14:07:07 for you during this deposition?
14:07:10 **A.** Yeah, I guess you could say that.
14:07:12 MR. GOSS: Object to form.
14:07:13 **A.** He just checked a reference for me. I was
14:07:16 trying -- We were both trying to find stuff.
14:07:18 **Q.** All right.
14:07:18 Do you know who Dr. Reed is?
14:07:20 **A.** Doctor who?
14:07:20 **Q.** Reed. Michael Reed?
14:07:23 **A.** I don't know him, but I know who he is,
14:07:25 yeah. He's --
14:07:26 **Q.** Okay. Are you aware he's doing a pilot
14:07:27 study for 3M right now?
14:07:29 MR. COREY GORDON: Object to the form of
14:07:31 the question.
14:07:31 **A.** I think that came up earlier, and I think I
14:07:33 had heard that it might be, but I don't have any
14:07:35 evidence or, let's say, direct knowledge of that.
14:07:38 **Q.** Do you know Dr. Harper?
14:07:40 **A.** No.
14:07:41 **Q.** Have you read any of his literature?
14:07:42 **A.** Don't think so.
14:07:43 **Q.** Okay. So have you read Dr. Reed's





14:07:54 deposition?
14:07:56 **A.** I think so, yeah.
14:07:58 **Q.** Have you read Dr. McGovern's deposition?
14:08:04 **A.** Yes.
14:08:04 **Q.** Have you read Dr. Legg's deposition?
14:08:06 **A.** I think so, yeah.
14:08:07 **Q.** Have you read Dr. Nachtsheim's deposition?
14:08:10 **A.** No.
14:08:10 **Q.** Have you read Dr. --
14:08:12 **A.** I don't remember. I may have, but I don't
14:08:13 remember.
14:08:14 **Q.** Have you read Dr. Legg's deposition?
14:08:17 **A.** I think so.
14:08:17 **Q.** So -- And you're aware, from reading
14:08:33 articles by Dr. Reed, that he has written articles
14:08:37 critical of the Bair Hugger safety; correct?
14:08:40 MR. COREY GORDON: Object to the form of
14:08:42 the question.
14:08:44 **A.** I'm not sure which articles you're referring
14:08:46 to.
14:08:46 **Q.** Well McGovern was -- Dr. Reed was on that;
14:08:49 correct?
14:08:49 **A.** Yes.
14:08:50 **Q.** And you're aware that actually Dr. McGovern
14:08:52 would be -- was more -- or Dr. Reed was more senior





14:08:54 than Dr. McGovern at the time.
14:08:56 **A.** That was my understanding.
14:08:57 **Q.** He was more of the advisor and overlooking
14:09:00 the whole study; correct?
14:09:01 **A.** Yeah.
14:09:01 **Q.** Okay. And you know that --
14:09:03 Are you aware that at one time Dr. Reed was
14:09:05 in Minneapolis and wanted to talk to the people at 3M
14:09:07 to discuss his findings?
14:09:09 MR. COREY GORDON: Object to the form of
14:09:10 the question, and assumes facts not in evidence.
14:09:11 **A.** I had heard that possibility, but I don't
14:09:14 know anything about that.
14:09:16 **Q.** And are you aware that 3M didn't want to
14:09:18 talk to him?
14:09:19 MR. COREY GORDON: Same objections.
14:09:20 **A.** I don't know that.
14:09:30 **Q.** Okay. Well I'm going to read you what the
14:09:32 objective of the study was, and tell me if it's...
14:09:44 MR. COREY GORDON: You talking about
14:09:45 McGovern?
14:09:45 MR. ASSAAD: No. The pilot study.
14:09:47 MR. COREY GORDON: Oh.
14:10:10 **Q.** Strike that.
14:10:10 Are you aware that 3M is funding a pilot





14:10:13 study in which they are assessing the risk of
14:10:19 postoperative orthopedic implant infection which may
14:10:23 be influenced by the choice of the intraoperative
14:10:26 warming technology?
14:10:27 **A.** I don't think I know that, no.
14:10:28 **Q.** Okay. Would that be information helpful to
14:10:32 you to see what the -- the data in that study, to
14:10:35 formulate your opinions of whether or not the Bair
14:10:38 Hugger has an effect on periprosthetic joint
14:10:41 infections?
14:10:43 **A.** So I don't --
14:10:44 What was the hypothesis of the study? And
14:10:46 you're asking me to --
14:10:46 **Q.** The hypothesis is this: We postulate that
14:10:49 the risk of postoperative orthopedic implant infection
14:10:52 may be influenced by the choice of intraoperative
14:10:56 warming technology. We plan to investigate this
14:10:58 through a multicenter superiority trial comparing
14:11:04 forced-air warming and resistive warming in adults
14:11:08 undergoing hemiarthroplasty following hip fracture.
14:11:13 Health/economic evaluations will form the secondary
14:11:16 aim of this study.
14:11:17 Are you aware that 3M is provi -- funding a
14:11:18 study?
14:11:19 **A.** No.

14:11:20 **Q.** Is that the type of study that might be
14:11:22 helpful in determining whether or not forced-air
14:11:26 warming has an effect on periprosthetic joint
14:11:29 infection?
14:11:29 MR. COREY GORDON: Object to the form of
14:11:30 the question.
14:11:30 **A.** Hard to know, but I love information. So if
14:11:33 you tell me there's more information out there, I'd
14:11:36 love to see it.
14:11:38 **Q.** Do you think a company should suppress
14:11:42 research regarding the safety of a device if there is
14:11:45 liti -- ongoing litigation regarding that device?
14:11:48 **A.** So hypothetically if there's ongoing
14:11:51 litigation a company tries to suppress?
14:11:54 **Q.** Research.
14:11:56 **A.** And this is hypothetical?
14:11:57 **Q.** Yes. Hypothetically.
14:11:59 **A.** Yeah.
14:12:00 **Q.** You think that's okay?
14:12:02 **A.** I don't think --
14:12:02 **Q.** Regarding the safety of a device.
14:12:02 **A.** Huh?
14:12:02 **Q.** Regarding the safety of a device.
14:12:05 **A.** Regarding the safety, hiding data?
14:12:06 **Q.** Or -- or not -- or not --





14:12:09 Or suppressing research.
14:12:10 **A.** Oh, suppressing research. I don't know the
14:12:14 details of what you're getting at here.
14:12:14 **Q.** Okay.
14:12:16 **A.** You're trying to say somebody suppressed
14:12:19 research maybe.
14:12:20 **Q.** Well hypothetically speaking, if a -- a
14:12:23 decision was made by 3M not to perform any research
14:12:27 regarding the safety and efficacy of the Bair Hugger
14:12:29 during this litigation, would you consider that being
14:12:34 responsible by a corporation?
14:12:36 **A.** Well I think the question is really do they
14:12:39 have information already on the safety and efficacy of
14:12:42 the Bair Hugger, and will this add more and they will
14:12:50 need it. I don't know. I'd like to see the whole
14:12:53 thing laid out and what the circumstances are for or
14:12:57 not.
14:13:18 **Q.** Can you identify one study that indicates
14:13:22 that the Bair Hugger does not cause periprosthetic
14:13:26 joint infections?
14:13:30 MR. COREY GORDON: Object to the form of
14:13:31 the question.
14:13:38 **A.** "Does not cause."
14:13:55 So I've put in my report, you know, I think
14:13:57 everything from the two clinical trials, but





14:14:02 periprosthetic. Certainly warming, I showed you the
14:14:10 study, I guess, from Holland.
14:14:14 **Q.** I'm just ask --
14:14:14 I'm asking one question.
14:14:15 **A.** Yeah.
14:14:15 **Q.** Just identify a study that indicates that
14:14:19 forced-air warming or the Bair Hugger does not cause a
14:14:23 periprosthetic joint infection.
14:14:25 MR. COREY GORDON: Object to the form of
14:14:25 the question.
14:14:27 **A.** Yeah. I mean, I can't come up with an
14:14:29 answer for that right now.
14:14:31 **Q.** Okay. And are you awa --
14:14:36 You've read Dr. Kurz's deposition; correct?
14:14:39 **A.** I have.
14:14:39 **Q.** You're aware that she told 3M that her 1996
14:14:42 study only applies to colorectal surgeries.
14:14:46 MR. COREY GORDON: Object to the form of
14:14:47 the question, misstates the evidence, assumes facts
14:14:49 not in evidence.
14:14:49 **A.** Don't remember what she told 3M, but that's
14:14:52 -- that's the study that she did was colorectal
14:14:55 patients.
14:14:55 **Q.** And it only applied to colorectal patients;
14:14:58 correct?





14:14:58 MR. COREY GORDON: Object to the form of
14:14:59 the question.
14:14:59 **A.** I don't know that she said that but, you
14:15:01 know, if she said I'm not sure that that would be so.
14:15:03 **Q.** And you're aware that Dr. Augustine and Dr.
14:15:07 Sessler used that information and marketed the Bair
14:15:10 Hugger across the world to increase sales.
14:15:12 MR. COREY GORDON: Object to the form of
14:15:14 the question, and assumes facts not in evidence.
14:15:16 **A.** I'm not aware that they did that, but if
14:15:19 that was the best data, and again if I --
14:15:22 **Q.** Well you love data, don't you?
14:15:24 **A.** I love data. That's why I'm saying it, for
14:15:27 you. If I -- You know, if I said to you, look, here's
14:15:29 a device that cuts down your infections by two thirds,
14:15:35 you're saying, well I'm getting a little different
14:15:37 operation than that one, I would still advise you this
14:15:42 is the best data.
14:15:43 **Q.** Where do you get that it cuts down by two
14:15:46 thirds?
14:15:46 **A.** You mean the Kurz study?
14:15:47 **Q.** Yeah.
14:15:48 **A.** Yes, 15 percent in five, I'm off by maybe a
14:15:51 little bit.
14:15:51 **Q.** Okay. And -- And you heard her say recently

14:15:53 that -- that that study would not be scientifically
14:15:57 valid today; correct?
14:16:00 MR. COREY GORDON: Object to the form of
14:16:00 the question and misstates the testimony.
14:16:01 **A.** I actually read the whole response that she
14:16:04 said, and then later on she was questioned. Did you
14:16:09 -- And she said, did I really say that? Because I --
14:16:13 You know, then she went on to say, I would need a
14:16:16 bigger study because, you know, so many things have
14:16:20 been done and everybody has to have a warmer. And the
14:16:22 second thing, she said it may not be two thirds, she
14:16:26 said 30 percent reduction is probably what I would see
14:16:29 today.
14:16:31 **Q.** In colo --
14:16:32 **A.** Still humongous, she said.
14:16:34 **Q.** Do you think there's a difference between
14:16:36 colorectal surgery and -- and a knee surgery?
14:16:38 MR. COREY GORDON: Object to the form of
14:16:40 the question.
14:16:40 **A.** Of course there's a difference, I mean. But
14:16:42 if you said does the skin react differently, you know,
14:16:47 or the microbiome, the body's physiology whether a
14:16:51 knife is on the abdomen or on a hip, I'm not sure.
14:16:55 **Q.** You think, sitting here today, that the
14:16:57 primary source of the bacteria in a colorectal surgery





14:17:02 which has a high incidence of infection, is the skin
14:17:05 and not the colon?
14:17:07 **A.** Well they had both, actually. When you look
14:17:09 at the organisms, if you found a Staph aureus, which
14:17:13 they certainly found, that was part of the finding.
14:17:16 That's not an organism commonly in the GI tract. Can
14:17:20 be. They also found enterococcus, they had one
14:17:24 candida. So they certainly had a mixture of what was
14:17:26 in the GI tract and what was on the skin. So if
14:17:29 that's what you're asking, yes.
14:17:30 **Q.** I mean you agree with me that colorectal
14:17:32 surgery has a high incidence of infection because it's
14:17:34 a -- whether it's a clean contaminated or a
14:17:37 contaminated surgery; correct?
14:17:38 **A.** That is correct.
14:17:39 **Q.** It's a much different surgery than a total
14:17:41 hip and total knee, --
14:17:42 **A.** It's --
14:17:42 **Q.** -- which is a clean surgery.
14:17:45 **A.** It's different from those operations, yeah.
14:17:47 But what I'm saying --
14:17:49 **Q.** Well that's all I -- that's all I need.
14:17:50 **A.** Okay.
14:17:51 **Q.** So, I mean, we agree that total hip and
14:17:53 total knee are considered clean surgeries.





14:17:55 **A.** Yes.
14:17:55 **Q.** Okay. With respect to the Leeming --
14:19:18 Leeming article that we just referenced, are you aware
14:19:21 that the biopsies of the skin were taken on the back?
14:19:24 **A.** No. I did -- you know, we -- this was a
14:19:27 very quick look and wanted to see the punch line.
14:19:30 **Q.** So you would agree with me that just assume
14:19:31 that I'm reading this correctly, that the samples were
14:19:34 taken on the back skin -- okay, the back -- the back
14:19:37 skin, that that doesn't indicate that there's data
14:19:40 that these types of bacteria are on the glands in the
14:19:45 knee or hip; correct?
14:19:47 **A.** If that's true, then that's what the study
14:19:50 would say.
14:19:50 **Q.** Okay.
14:19:51 **A.** I'm not questioning your...
14:19:54 **Q.** All right.
14:19:54 (Mr. Ben Gordon departed the proceedings.)
14:20:45 **Q.** And as an expert that's doing a literature
14:20:48 review, the best evidence to rely upon are going to be
14:20:54 peer-reviewed studies; correct?
14:20:56 MR. COREY GORDON: Object to the form of
14:20:58 the question.
14:20:58 **A.** In general I think that's better.
14:21:01 **Q.** Because there are many studies that are





14:21:03 performed, even internally at 3M, that they might just
14:21:07 be trying to determine which is the best way to study
14:21:12 and might try different types of techniques; correct?
14:21:17 **A.** Yeah, I don't know what 3M's doing in trying
14:21:17 to come up with techniques.
14:21:18 **Q.** But, for example, let's talk about, you
14:21:26 know, culturing glands, okay? Let's see what grows in
14:21:29 glands. There might be some techniques that work to
14:21:31 determine whether or not there's bacteria in the
14:21:33 glands, and there might be other techniques that might
14:21:35 not work; correct?
14:21:37 MR. COREY GORDON: Object to the form of
14:21:37 the question.
14:21:37 **A.** Hypothetically, yes.
14:21:39 **Q.** And as a scientist you're trying to
14:21:41 determine, you know, if you want to collect data,
14:21:44 which is the best way to collect data; correct?
14:21:49 **A.** I'd like to know the best way always.
14:21:51 **Q.** Okay. And sometimes you might try a method
14:21:54 that might not work; correct?
14:21:56 **A.** Happens all the time.
14:21:57 **Q.** Okay. Happens all the time.
14:21:59 And when you try a method that doesn't work,
14:22:01 do you publish that?
14:22:02 **A.** You might.

14:22:03 **Q.** You may if you've gone through a whole
14:22:06 study; correct?
14:22:07 **A.** You might.
14:22:08 **Q.** Okay. But you might not publish it;
14:22:11 correct?
14:22:12 MR. COREY GORDON: Object to the form of
14:22:13 the question, incomplete hypothetical.
14:22:15 **A.** I don't -- I don't know. I -- If you're
14:22:18 getting to the maybe seven studies that were done by
14:22:24 Dr. Reed and Dr. -- and his colleagues that were not
14:22:27 published that were important data, then I probably
14:22:33 won't agree with you.
14:22:35 **Q.** Oh. So you could have unpublished data
14:22:37 that's important?
14:22:40 **A.** I guess what I'm saying is --
14:22:42 **Q.** Is that what you're saying?
14:22:43 Answer my question, please?
14:22:44 MR. COREY GORDON: He's about to answer
14:22:47 your question.
14:22:47 **A.** No. I'm trying --
14:22:47 MR. COREY GORDON: Don't cut him off.
14:22:47 **A.** I'm trying to answer your question. So
14:22:47 let's go back to --
14:22:50 MR. ASSAAD: Simple question.
14:22:50 **A.** Let's go back to particles --





14:22:51 MR. ASSAAD: A very simple question.
14:22:55 **Q.** Okay. I'm talking to my colleague.
14:22:56 **A.** Yeah, that's fine.
14:22:57 **Q.** I'm just saying it was a simple question,
14:22:59 but you go ahead and answer.
14:23:01 **A.** Okay. So, you know, one of the studies, you
14:23:04 know, a series of studies that looked at particles as
14:23:10 opposed to bacteria. And the real question is just,
14:23:16 you know, you might find more particles, you might
14:23:18 find more heat, you might find, you know, smoke, for
14:23:23 example, but if the -- the question then is, do -- are
14:23:29 the particles actually associated or linked with the
14:23:32 colony-forming units.
14:23:33 So in my report I have eight studies that
14:23:36 show that no obvious signal, at least with the Bair
14:23:40 Hugger in use, that you're going to get colony-forming
14:23:45 units. And then through discovery find out that there
14:23:50 were seven studies, you know, for the other side, if
14:23:53 you will, that were not published that also showed you
14:23:58 cannot find colony-forming units when the Bair Hugger
14:24:01 is in use.
14:24:03 So when you say that -- that the
14:24:05 peer-reviewed literature is important, I totally
14:24:07 agree, I want that. But if there are other studies,
14:24:10 and I've shown you the seven, including ones where the





14:24:16 authors said, look, we tried three different ways in
14:24:19 five different studies to try to find colony-forming
14:24:21 units when the Bair Hugger was working, we couldn't.
14:24:24 So collectively I think those are use -- useful data.
14:24:30 **Q.** Did you look at the studies?
14:24:32 **A.** I did.
14:24:33 **Q.** Okay. And they were not peer reviewed;
14:24:38 correct?
14:24:39 **A.** Don't even know I -- whether how many were
14:24:42 even sent for peer review. You mean the seven that
14:24:45 I'm talking about?
14:24:46 **Q.** Were you provided any studies from 3M
14:24:48 internally?
14:24:49 **A.** No.
14:24:49 **Q.** Okay. So 3M just provided you the studies
14:24:51 to call -- talk about hidden studies of actual
14:24:56 researchers that are trying to solve a problem, and
14:24:58 they did not provide important internal studies that
14:25:00 they have; correct?
14:25:02 **A.** Well --
14:25:02 MR. COREY GORDON: Object to the form of
14:25:04 the question.
14:25:04 THE WITNESS: Yeah.
14:25:04 **A.** Well I guess what I found out about the
14:25:05 studies was primarily through the depositions.





14:25:08 **Q.** That wasn't my question. Just please answer
14:25:09 my question.
14:25:09 **A.** Yeah.
14:25:10 **Q.** Did they provide you studies or not?
14:25:12 **A.** Okay. Look. Maybe I didn't understand. Go
14:25:12 ahead.
14:25:12 **Q.** Did they provide you internal studies? Just
14:25:13 answer my question, sir.
14:25:13 MR. COREY GORDON: Asked -- Objection --
14:25:15 (Interruption by the reporter.)
14:25:16 MR. COREY GORDON: Objection, asked and
14:25:17 answered.
14:25:18 **Q.** Did they provide you any internal studies?
14:25:20 MR. COREY GORDON: Objection, asked and
14:25:22 answered.
14:25:22 MR. ASSAAD: Fair enough.
14:25:24 **A.** So internal studies, I don't think I saw
14:25:26 anything from 3M.
14:25:33 **Q.** And please, doctor, listen to my questions.
14:25:35 **A.** I'll try better.
14:25:36 **Q.** We have very few hours left. Let's not try
14:25:39 to go on tangents.
14:25:43 Are you aware that 3M manipulated particle
14:26:18 data that they -- on a study that they funded?
14:26:23 MR. COREY GORDON: Object to the form of

14:26:23 the question, assumes facts not in evidence.
14:26:24 **A.** Don't know anything about that.
14:26:25 **Q.** So 3M did not provide you the data that they
14:26:28 did particle tests out in Holland?
14:26:30 MR. COREY GORDON: Same objections.
14:26:30 **A.** I don't have that data.
14:26:32 **Q.** Okay. Are you surprised that that data
14:26:34 exists?
14:26:34 MR. COREY GORDON: Same objections.
14:26:35 **A.** I don't know how to answer that. I have --
14:26:37 just haven't gotten it yet.
14:26:39 **Q.** Are you aware that 3M funded a study to do
14:26:42 the effects of the Bair Hugger on particles in a
14:26:46 laminar operating room?
14:26:48 **A.** No.
14:26:49 **Q.** Did you do independent research to determine
14:26:52 whether or not there were particle tests conducted on
14:26:56 the Bair Hugger?
14:26:57 **A.** Did I do research?
14:26:58 **Q.** Yeah.
14:26:59 **A.** No. I -- Everything that I did is in my
14:27:02 report.
14:27:02 **Q.** So you did not do any PubMed searches or
14:27:05 researches to search with particle tests for a Bair
14:27:08 Hugger?





14:27:08 MR. COREY GORDON: Object to the form of
14:27:10 the question.
14:27:10 **A.** Yeah, I did. I -- I think I have those
14:27:13 listed.
14:27:14 **Q.** You don't have the Dr. Sessler and Russ
14:27:16 Olmsted study; do you?
14:27:18 **A.** No, I don't think so.
14:27:19 **Q.** Okay. So the one study that was funded by
14:27:22 3M, you don't have.
14:27:24 **A.** Correct.
14:27:24 MR. COREY GORDON: Object to the form of
14:27:25 the question.
14:27:26 THE WITNESS: I'm sorry.
14:27:27 **Q.** That was done in 2011. You don't have that
14:27:29 study.
14:27:29 **A.** I don't think I have that study.
14:27:30 **Q.** Okay. Are you aware that 3M has relied
14:28:00 heavily on the Sessler study in trying to market the
14:28:08 Bair Hugger device and its safety?
14:28:10 MR. COREY GORDON: Object to the form of
14:28:12 the question, also assumes facts not in evidence.
14:28:13 **A.** No, I don't know any of that.
14:29:18 **Q.** Doctor, you are aware that many orthopedic
14:29:21 surgeons care about increase of particles in -- above
14:29:24 the surgical site.





14:29:26 MR. COREY GORDON: Object to the form of
14:29:27 the question, also lack of foundation.
14:29:28 **A.** I don't know what they think about
14:29:29 particles, no.
14:29:31 **Q.** I mean, have you worked with orthopedic
14:29:34 surgeons in the past?
14:29:35 **A.** Only clinically --
14:29:35 **Q.** When you say clini --
14:29:37 **A.** -- where you take care of their patients.
14:29:39 **Q.** After they've had the infection; correct?
14:29:40 **A.** That's correct, yeah.
14:29:41 **Q.** Okay. Do the numbers of bacteria arriving
14:30:09 in the surgical wound correlate directly with the
14:30:12 probability of surgical-site infection?
14:30:16 **A.** Well I would point to Stocks article first,
14:30:19 and he has a correlation for those particles that are
14:30:24 greater than 10 microns in size. And then there is
14:30:28 the study we talked about, the Darouiche study, that
14:30:32 modeled bacteria and particles.
14:30:37 **Q.** So you agree with Stocks' paper?
14:30:40 MR. COREY GORDON: Object to the form of
14:30:41 the question.
14:30:41 **A.** Let me -- Let me -- Let me finish.
14:30:43 You know, and then there's Birgand's study
14:30:46 who in fact shows the correlation between -- in





14:30:48 general between particles and bacteria. But he also
14:30:52 did something else, he looked at the relationship
14:30:55 between the number of particles in the air and the
14:31:01 contamination of the wound. That did not correlate at
14:31:03 all. So Birgand talked about those studies in his
14:31:11 article that there were many that showed a correlation
14:31:14 and also many that didn't show a correlation.
14:31:19 **Q.** So can you answer my question "yes" or "no"?
14:31:21 I want to know what your opinion is, not what other
14:31:23 people say.
14:31:23 **A.** No. I understand. I mean I'm --
14:31:26 MR. COREY GORDON: Let him finish his --
14:31:29 **Q.** I could read their -- I could their
14:31:29 articles.
14:31:29 **A.** Yeah.
14:31:30 **Q.** My question is: Does Dr. Wenzel, you, do
14:31:35 you agree that the number of bacteria arriving in the
14:31:38 surgical wound correlate directly with the probability
14:31:41 of surgical-site infection?
14:31:43 MR. COREY GORDON: Object to the form of
14:31:44 the question, move to strike counsel's commentary.
14:31:46 **A.** So when you say those, you're talking about
14:31:49 the studies that correlate particles and bacteria are
14:31:51 those that land in the wound, --
14:31:51 **Q.** I am talking --

14:31:53 **A.** -- you're saying?
14:31:53 **Q.** -- about -- not the studies, I'm talking about what Dr. Wenzel's opinion is.
14:31:56
14:31:59 **A.** Yeah.
14:31:59 **Q.** Okay. Based on what whatever you've read.
14:32:02 **A.** Yeah.
14:32:02 **Q.** Okay. I don't want to know the studies, I know what the studies are. Because I know some of them you agree with and some of them you don't agree with; correct?
14:32:05
14:32:06
14:32:09
14:32:11 **A.** That's right.
14:32:11 **Q.** Okay. So I want to know what your opinion is, not what the studies' opinion is.
14:32:13
14:32:13 **A.** Umm-hmm.
14:32:15 **Q.** Fair enough?
14:32:15 **A.** Yeah.
14:32:16 **Q.** Okay. Does Dr. Wenzel agree, you, that the number of bacteria arriving in the surgical wound correlate directly with the probability of a surgical-site infection?
14:32:20
14:32:23
14:32:26
14:32:28 **A.** I can't answer that for all studies, there is a disparity of that. But my opinion is that it's not been linked to surgical-site infections. Particles and bacteria have been linked, but not necessarily that link of CFUs and infection.
14:32:31
14:32:36
14:32:39
14:32:42





14:32:46 **Q.** I wasn't talking about particles.
14:32:48 Listen to the question.
14:32:49 **A.** Yeah. Go ahead.
14:32:50 **Q.** Do the numbers of bacteria arriving in the surgical wound correlate directly with the probability of surgical-site infection; "yes" or "no"?
14:32:54
14:32:57
14:33:01
14:33:07 **A.** Well Birgand would say no, he can't find a correlation with contamination of the wound.
14:33:09 **Q.** What about Dr. Wenzel?
14:33:11 **A.** I don't know.
14:33:12 **Q.** Okay. You don't know.
14:33:12 **A.** I mean, I'm not sure.
14:33:13 **Q.** Okay. What about this question: Do the number of bacteria in the operating room environment correlate directly with the probability of SSI, "yes" or "no," according to Dr. Wenzel?
14:33:16
14:33:19
14:33:24
14:33:25 MR. COREY GORDON: Object to the form of the question, incomplete hypothetical. It's not a yes-or-no question.
14:33:27
14:33:29
14:33:33 **Q.** "Yes" or "no"?
14:33:34 **A.** So the total number of bacteria in the air?
14:33:36 **Q.** I'll read it again.
14:33:37 **A.** Yeah.
14:33:38 **Q.** Do numbers of bacteria in the operating room environment correlate directly with the probability of
14:33:42





14:33:46 surgical-site infections?
14:33:47 **A.** I haven't seen that, no.
14:33:48 **Q.** So you disagree --
14:33:48 **A.** I don't know.
14:33:49 **Q.** -- with that.
14:33:50 **A.** I don't know.
14:33:51 **Q.** You don't know. Okay.
14:33:52 You don't have an opinion whether or not OR traffic increases the risk of surgical-site infection; is that correct?
14:34:34
14:34:39
14:34:40 **A.** I think in general OR traffic's been linked to increasing particles. It's hard to know whether those increased surgical-site infections, but I think there are some studies. I'm having trouble remembering which ones show that it might, but it might be important. But then there is some contradictory evidence and I was just, in my report, trying to show that.
14:34:43
14:34:45
14:34:50
14:34:52
14:34:54
14:34:57
14:35:01
14:35:02 **Q.** Well just so I understand, at trial you're not going to have an opinion that OR traffic caused a surgical-site infection.
14:35:05
14:35:12
14:35:15 MR. COREY GORDON: Object to the form of the question.
14:35:17
14:35:20 **A.** At this point I don't know. Yeah.
14:35:23 **Q.** Well I --





14:35:24 **A.** Yeah.
14:35:24 **Q.** -- here's the thing, doctor, and I'm not trying to be difficult. I know the studies as well as you do.
14:35:26
14:35:29
14:35:29 **A.** Yeah.
14:35:30 **Q.** Okay. And -- Not as well, but I know them fairly well. You probably know them better.
14:35:33
14:35:35 I'm not -- I could read the studies as well. I want to know based on your reading of the studies what Dr. Wenzel's opinion is, okay? Not what the literature says, but what your opinion is. You could support it with the literature, but at this point in time I've read your report, I know what literature you're relying upon.
14:35:37
14:35:39
14:35:42
14:35:44
14:35:46
14:35:49
14:35:50 I just want to know, okay, do you think that OR traffic increases the risk of surgical-site infections in a total hip or total knee arthroplasty?
14:35:56
14:36:03
14:36:06 **A.** It might, yes.
14:36:07 **Q.** It might --
14:36:07 **A.** Yeah.
14:36:07 **Q.** -- or it does?
14:36:08 **A.** I don't know. It might.
14:36:09 **Q.** Can you say that within a reasonable degree --
14:36:11
14:36:11 **A.** Yeah.

14:36:11 **Q.** -- of medical probability?
14:36:12 **A.** Yeah, I think so.
14:36:13 **Q.** Okay. So if that's the case, then you have
14:36:15 to agree that the -- the OR traffic increases
14:36:20 particles, and therefore increases the bacterial load
14:36:23 in the operating room; correct?
14:36:25 MR. COREY GORDON: Object to the form of
14:36:26 the question.
14:36:26 **A.** According to some people who've shown
14:36:28 correlations.
14:36:30 **Q.** Well do you agree with that?
14:36:32 **A.** They'll show correlations with particles and
14:36:34 CFUs in some studies, and I've already talked about
14:36:37 those.
14:36:37 **Q.** I'm just saying with the OR traffic.
14:36:40 Do you agree that the OR traffic has -- has
14:36:48 an effect on surgical-site infections in total knee or
14:36:54 total hip arthroplasty?
14:36:55 MR. COREY GORDON: Object to the form of
14:36:55 the question, --
14:36:55 **A.** It might.
14:36:56 MR. COREY GORDON: -- also asked and
14:36:56 answered.
14:36:57 **Q.** It might. Okay.
14:36:58 And it may not; correct?





14:36:59 **A.** Yeah.
14:37:00 **Q.** Okay. So sitting here today you don't know
14:37:02 one way or the other.
14:37:02 **A.** Yeah.
14:37:03 **Q.** Okay. Going on.
14:37:25 Do you agree that the incidence of
14:37:36 periprosthetic joint infection is related to surgical
14:37:39 time?
14:37:40 **A.** Surgical time has been shown to be a risk
14:37:43 factor, yes.
14:37:44 **Q.** So Dr. Wenzel agrees with that.
14:37:47 **A.** Yeah.
14:37:47 **Q.** Okay.
14:37:47 **A.** I have a example of that in my section on
14:37:50 risk factors.
14:38:08 **Q.** Do you agree there still needs to be further
14:38:11 research with per -- with respect to the effects of
14:38:18 hypothermia on periprosthetic joint infection?
14:38:22 MR. COREY GORDON: Object to the form of
14:38:23 the question.
14:38:24 **A.** Well, you know I love data. Any more
14:38:28 information that would be added to what I -- what we
14:38:32 have here, I'm always -- I mean, there's never -- I'm
14:38:34 never going to say, no, don't do a study.
14:38:37 **Q.** I understand that.





14:38:38 But you're not going to do a study if you
14:38:40 know the answer; correct?
14:38:42 MR. COREY GORDON: Object to the form of
14:38:42 the question.
14:38:44 **Q.** You do a study to find out the answer.
14:38:46 **A.** Yeah, you do, and -- but you always want
14:38:48 confirmation, I think. I guess that's what I'm
14:38:51 saying.
14:38:51 **Q.** I understand that. But are you -- But
14:38:54 sitting here today you cannot state, with any degree
14:38:58 of medical certainty, that maintaining normothermia
14:39:06 reduces the incident of periprosthetic joint infection
14:39:09 because that has never been looked at; correct?
14:39:12 MR. COREY GORDON: Object to the form of
14:39:12 the question.
14:39:13 **A.** So that part is true, they haven't studied
14:39:16 just joints in a prospective way, yes.
14:39:18 **Q.** So further research would be needed to
14:39:20 answer that question.
14:39:21 **A.** Further research would really help answer
14:39:24 it.
14:39:25 **Q.** Okay. Are you aware that 3M never did a
14:39:44 safety validation of the Bair Hugger device?
14:39:47 MR. COREY GORDON: Object to the form of
14:39:49 the question, lack of foundation, assumes facts not





14:39:51 in evidence.
14:39:52 **A.** I'm not.
14:39:53 **Q.** Are you aware that the Bair Hugger device
14:39:55 was based off a 1937 cast warmer?
14:39:59 MR. COREY GORDON: Object to the form of
14:40:00 the question.
14:40:01 **A.** No, I didn't know that.
14:40:02 **Q.** Okay. Are you aware that the older Bair
14:40:12 Hugger device warned for air -- airborne
14:40:16 contamination?
14:40:16 MR. COREY GORDON: Object to the form of
14:40:19 the question, assumes facts not in evidence.
14:40:21 **A.** Say that again.
14:40:21 **Q.** That the older version, the mod -- the
14:40:21 series 200 Bair Hugger devices warned about airborne
14:40:24 contamination?
14:40:24 MR. COREY GORDON: Same objections.
14:40:26 **A.** And I don't know that. I don't re --
14:40:29 **Q.** Are you aware that competing products of the
14:40:30 Bair Hugger, such as the Mistral, that are forced-air
14:40:36 warming, warn about airborne contamination?
14:40:37 **A.** Don't know that either.
14:40:38 **Q.** Would that influence your opinion in any
14:40:40 way?
14:40:40 **A.** I'd have to see what they say.

14:40:42 **Q.** Okay. But the --
14:40:44 But 3M has not shown you that information;
14:40:45 correct?
14:40:46 **A.** I haven't seen that.
14:40:48 **Q.** And you love data; correct?
14:40:50 **A.** I do.
14:40:50 **Q.** I mean, you -- the more data the better for
14:40:52 you; right?
14:40:53 **A.** I like it.
14:40:53 **Q.** I mean, you spent over 300 hours going
14:40:56 through data; correct?
14:40:57 **A.** That's true.
14:40:57 **Q.** And if you had to do a hundred hours more
14:41:00 you would do it; correct?
14:41:01 **A.** I love it.
14:41:01 **Q.** Love data.
14:41:02 And if 3M gave you more data you would have
14:41:08 reviewed it; right?
14:41:09 **A.** I would.
14:41:10 **Q.** Okay. And so sitting here today do you
14:41:19 agree with me that there is some data that 3M did not
14:41:22 provide you?
14:41:22 MR. COREY GORDON: Object to the form of
14:41:23 the question, assumes facts not in evidence, lack of
14:41:26 foundation.





14:41:26 **A.** I don't know that.
14:41:26 **Q.** Okay. Are you familiar with the
14:42:29 international consensus of orthopedics that discuss
14:42:34 periprosthetic joint infections?
14:42:35 **A.** I don't think I know that.
14:42:37 **Q.** It was sponsored by 3M.
14:42:39 MR. COREY GORDON: Object to the form of
14:42:41 the question, mischaracterizes the evidence.
14:42:44 **A.** You're asking if I know that? I don't.
14:42:46 **Q.** Okay. Do you know who Dr. Parvizi is?
14:42:49 **A.** I know who he is, yeah.
14:42:52 **Q.** Okay. Do you know --
14:42:53 You know Dr. Gregory Stocks; correct?
14:42:55 **A.** I don't know him, no.
14:42:56 **Q.** But you've read his -- his -- you know who
14:42:58 he is.
14:42:58 **A.** Yes.
14:42:59 **Q.** Okay. And you've actually cited to one of
14:43:02 his articles; correct?
14:43:03 **A.** I did.
14:43:03 **Q.** Okay. And you would consider him an expert
14:43:05 in orthopedic surgery; correct?
14:43:05 MR. COREY GORDON: Object to the form of
14:43:09 the question, lack of foundation.
14:43:09 **A.** I don't know if he's an expert or not in





14:43:11 orthopedic surgery.
14:43:15 **Q.** Are you aware that the general consensus
14:44:10 among orthopedic surgeons have the opinion that
14:44:18 periprosthetic joint infections are caused by airborne
14:44:20 contaminants?
14:44:21 MR. COREY GORDON: Object to the form of
14:44:23 the question, lack of foundation, mischaracterizes,
14:44:24 assumes facts not in evidence.
14:44:26 **A.** No, I'm not aware of their general opinions.
14:45:33 MR. ASSAAD: Let's take a break.
14:45:35 THE REPORTER: Off the record, please.
14:45:37 (Recess taken from 2:45 to 2:55 p.m.)
14:55:50 BY MR. ASSAAD:
14:56:03 **Q.** One of your critiques of the McGovern study
14:56:06 was the change in anti -- the prophylactic
14:56:13 anticoagulant; correct?
14:56:14 **A.** Yes.
14:56:17 **Q.** Okay. Are you aware of any studies that
14:56:20 compared the two -- the two drugs used in McGovern for
14:56:31 anticoagulation and compared with infection rates?
14:56:36 **A.** I thought that Brimmo's study actually
14:56:41 looked at the two, Rivaroxaban versus other
14:56:46 anticoagulants.
14:56:50 Now, you know, did -- your question partly
14:56:52 was did it go only with enoxaparin. I don't think so.





14:57:00 I think there were options. The infection rate of
14:57:02 course was two and a half percent versus .2 percent --
14:57:06 or the, you know, with rivaroxaban the high number,
14:57:12 and the other anticoagulants .2 percent, which was
14:57:16 significant.
14:57:19 So independent of the McGovern study I guess
14:57:26 there were two parts of that study. I mean, Jensen's
14:57:31 study was separate, and he found two and a half
14:57:35 percent versus I think one percent, again with
14:57:42 rivaroxaban. And then somewhere along the line, I
14:57:45 think it was Albrecht who said, if you keep the
14:57:52 antibiotics constant you get something like 4.2
14:57:57 percent versus 1.7 percent.
14:57:59 So these are the data that come to mind
15:58:03 comparing rivaroxaban versus enoxaparin, or rather the
15:58:11 -- the alternative.
14:58:13 **Q.** Are you awa -- Okay. Let's go to your
14:58:15 Exhibit Number 2, your Exhibit B.
14:58:17 **A.** What am I going to?
14:58:18 **Q.** Your document list.
14:58:20 **A.** Oh.
14:58:25 **Q.** And you mention the Berrios-Torres article,
14:58:31 *Centers for Disease Control and Prevention Guideline*
14:58:32 *For the Prevention of Surgical Site Infection* 2017 as
14:58:36 being authoritative?

14:58:37 **A.** Which number is this?
14:58:38 **Q.** Exhibit Number 2.
14:58:40 **A.** I'm sorry.
14:58:43 **Q.** It's a list of documents you considered.
14:58:44 **A.** Yeah.
14:58:47 **Q.** Remember we talked about the CDC?
14:58:49 **A.** Yeah.
14:58:49 **Q.** Okay. And you thought it was authoritative?
14:58:52 Are you aware that in this article it
14:58:54 states, high-quality evidence suggested no difference
14:58:58 between injectable enoxaparin and oral rivaroxaban and
14:59:03 risk of SSI?
14:59:06 **A.** I think I do remember that, yeah.
14:59:07 **Q.** Okay. And you're disregarding that.
14:59:10 **A.** No, I'm not -- I wouldn't disregard
14:59:11 anything.
14:59:12 **Q.** And this was based on no difference in SSI
14:59:14 in a large meta-analysis, 12,383 patients of four,
14:59:23 random controlled trials in elective primary or
14:59:26 revision total hip or total knee arthroplasty, and no
14:59:30 difference in hemorrhagic wound complications or
14:59:35 drug-related adverse effects.
14:59:35 Do you disagree with that or agree with
14:59:37 that?
14:59:37 MR. COREY GORDON: What are you reading





14:59:38 from?
14:59:39 **Q.** He knows where I'm reading from.
14:59:40 **A.** So I think you're referring to the capital
14:59:42 studies, or what are they called, the RECORD studies,
14:59:45 I guess. Is that the reference that you're talking
14:59:49 about, CDC said that?
14:59:50 **Q.** They're referring to --
14:59:51 **A.** The four large studies?
14:59:53 **Q.** Eriksson, Kakkar?
14:59:57 **A.** I think they're all part of the RECORD
14:59:59 studies.
15:00:00 **Q.** And do you disagree with the CDC?
15:00:03 **A.** Well I think I have to clarify that, because
15:00:05 Jensen did a study, and he said unfortunately the
15:00:10 RECORD studies didn't do a very good job looking at
15:00:13 surgical-site infections, and that's why -- that's
15:00:15 prompted him to do a study.
15:00:17 **Q.** So you disa --
15:00:17 **A.** And Bremo --
15:00:19 **Q.** You disagree with the CDC.
15:00:19 **A.** I think it needs some clarification, in that
15:00:23 sense.
15:00:23 **Q.** So --
15:00:23 But you disagree with their statement that
15:00:25 high quality -- high quality --





15:00:28 **A.** Yeah.
15:00:29 **Q.** -- evidence suggested no difference between
15:00:31 injectable enoxaparin and oral rivaroxaban and risk of
15:00:35 SSI.
15:00:37 Do you agree or disagree with the CDC?
15:00:39 **A.** So that's what they found, that's what they
15:00:41 believe. I was just trying to clarify, and I don't
15:00:44 necessarily disagree with them, I have a different
15:00:47 interpretation based on, you know, the studies of
15:00:51 Jensen and Brimmo.
15:00:53 **Q.** What was the number of people in those
15:00:55 populations in Jensen?
15:00:57 **A.** They were -- They were much smaller than the
15:00:58 thousands in this.
15:01:00 **Q.** 12,383.
15:01:01 **A.** Yeah.
15:01:02 **Q.** Okay.
15:01:02 **A.** But -- But again, I just want to point out,
15:01:05 when Jensen opens up his article he said, look, we
15:01:08 don't have a good handle on surgical-site infections.
15:01:10 They focused on bleeding, they focused on which was a
15:01:14 comparable or a different thromboprophylaxis from the
15:01:20 point of view of a DVT or a pulmonary embolus. And
15:01:23 then Borak, when he was asked similar questions, said
15:01:26 he couldn't even find the definition that they used.





15:01:29 And so it comports with the same finding that Jensen
15:01:35 said in his study, and the same for Brimmo. They both
15:01:41 think that --
15:01:41 **Q.** What's Dr. Wenzel's opinion? Does -- Is
15:01:44 there a difference in the risk of surgical-site
15:01:48 infection between rivaroxaban and enoxaparin?
15:01:51 MR. COREY GORDON: You're asking about
15:01:52 enoxaparin, --
15:01:52 **A.** Yeah. Not --
15:01:52 MR. COREY GORDON: -- not tinzaparin.
15:01:52 **A.** Yeah.
15:01:56 **Q.** I'm asking.
15:01:56 **A.** Yeah. I mean, in those studies CDC is
15:02:00 probably right.
15:02:06 **Q.** And you're aware that the CDC put
15:02:09 enoxaparin, dalteparin, tinzaparin and fondaparinux as
15:02:16 one category.
15:02:17 **A.** I didn't know, but I'm not surprised.
15:02:19 **Q.** Because they're all the same pretty much;
15:02:20 correct?
15:02:21 **A.** I think they're --
15:02:23 MR. COREY GORDON: Object to the form of
15:02:23 the question.
15:02:22 **A.** -- in the same family.
15:02:24 **Q.** The same family.

15:02:27 Turning to page 73 of your report. Is page
15:02:50 73 the entire critique, in your report, of Dr. Jarvis?
15:02:59 **A.** Did I write anything else; is that what
15:03:00 you're asking?
15:03:01 **Q.** Yes.
15:03:01 **A.** I think I don't have anything else in the
15:03:03 report.
15:03:04 **Q.** And would --
15:03:05 And would you agree with me that the bottom
15:03:07 of page 73 and 74 is your entire critique of Dr.
15:03:10 Samet?
15:03:11 **A.** Yeah.
15:03:12 MR. COREY GORDON: Object to the form of
15:03:13 the question.
15:03:32 **Q.** Now you would agree with me, doctor, that
15:03:36 the majority of the articles that you cite deal more
15:03:39 with superficial surgical-site infections and not
15:03:48 periprosthetic joint infections.
15:03:50 **A.** Yeah. I haven't counted them up, but many
15:03:52 of them deal with su -- with the superficial
15:03:54 infections.
15:03:55 **Q.** And even though they're both infections,
15:04:01 there is some difference in the mechanism of cause.
15:04:07 **A.** I'm not sure that's correct. In other
15:04:10 words, my own concept is the initiation of infection





15:04:13 is quite similar. You have an or -- an organism
15:04:17 that's part of the flora; to me that's the origin in
15:04:20 both. The organism gets to the wound; that's the
15:04:24 same. And it's there at -- usually at the time of
15:04:27 incision.
15:04:29 After that, as I said, once the organism
15:04:32 gets on the vascular prosthetic device it begins to go
15:04:38 through some changes through quorum sensing, it does
15:04:41 build up the biofilm, and that's different, vastly
15:04:45 different.
15:04:46 **Q.** I understand that.
15:04:46 But you agree one of the differences is the
15:04:49 quantity of bacteria required to cause the infection.
15:04:53 **A.** I think it's fewer bacteria to cause an
15:04:56 infection with the prosthesis.
15:04:59 **Q.** And -- And one of the reasons is because
15:05:00 when you have, for example, prophylactic antibiotics
15:05:05 as well as the host immune system, that's much more
15:05:10 effective at eliminating or attacking the bacteria
15:05:13 than on a device that has no vascularity and therefore
15:05:19 the host can't fight it off; correct?
15:05:22 MR. COREY GORDON: Objection, asked and
15:05:23 answered.
15:05:23 **A.** Yeah, the way that I would -- yeah, I would
15:05:25 say if you can't control the microbiome you're going





15:05:27 to get infections.
15:05:57 **Q.** Let's go to page 3.
15:05:59 **A.** Okay. Yeah.
15:06:15 **Q.** The chart you have on page 3, Figure 1, is
15:06:17 right out of the 1996 Kurz study; correct?
15:06:20 **A.** Yes.
15:06:20 **Q.** Okay. You would agree with me that the
15:06:23 first hour that a patient's being warmed the patient
15:06:26 still becomes hypothermic in colorectal surgeries.
15:06:30 **A.** I think that's --
15:06:32 You know, if you ask what proportion of the
15:06:34 time, I don't know, but they are hypothermic for
15:06:37 awhile.
15:06:37 **Q.** Okay. Even with forced-air warming.
15:06:39 **A.** Umm-hmm.
15:06:40 **Q.** Is that a "yes"?
15:06:41 **A.** Yes.
15:06:41 **Q.** Okay.
15:06:41 **A.** Sorry.
15:06:44 **Q.** And you recall Dr. Kurz, in her deposition,
15:06:48 discussing the types of infections that they were
15:06:53 counting with respect to -- to calculate the incident
15:06:59 of infection with forced-air warming and without
15:07:00 forced-air warming. Do you recall that testimony?
15:07:02 **A.** No, --





15:07:03 MR. COREY GORDON: Object to the form of
15:07:04 the question.
15:07:02 **A.** -- I don't remember that.
15:07:04 **Q.** Do you recall her stating that many of the
15:07:06 infections that they were identifying were
15:07:15 non-clinically significant infections?
15:07:16 MR. COREY GORDON: Object to the form of
15:07:18 the question, mischaracterizes --
15:07:19 **A.** I don't remember that, --
15:07:19 MR. COREY GORDON: -- the evidence.
15:07:19 **A.** -- but I'd be happy to look at it again.
15:07:21 **Q.** You would defer to Dr. Kurz with respect to
15:07:24 the interpretation of her own study; correct?
15:07:26 MR. COREY GORDON: Object to the form of
15:07:26 the question.
15:07:27 **A.** Yeah. You know, we talked about this
15:07:28 earlier where she changed her opinion, you know,
15:07:31 through the start, so, but I -- yeah, in general she
15:07:35 called that -- whatever she called the infection I
15:07:37 would defer to her.
15:07:38 **Q.** Okay. Just like when you have a question
15:07:42 about a study, you call the author of the study and
15:07:44 ask questions; correct?
15:07:45 **A.** I do sometimes.
15:07:46 **Q.** Like you did with Dr. Darouiche.

15:07:48 **A.** I do.
15:07:49 **Q.** Okay. And with Dr. Chen; correct?
15:07:54 **A.** Yes.
15:07:54 **Q.** Okay. Because for the most part the person
15:08:00 that conducted the study knows more about the study
15:08:05 that was -- that was done; correct?
15:08:07 **A.** That's true.
15:08:08 **Q.** Okay. Now with respect to the oxygenation
15:08:41 issue and the benefits of oxygenation by using
15:08:44 forced-air warming, none of those studies looked at
15:08:47 periprosthetic joint infections; correct?
15:08:49 **A.** I think that's true.
15:08:50 **Q.** Okay. And you agree with me that when
15:09:12 Andrea Kurz indicated in her deposition with respect
15:09:16 to what would happen if you did the study now and it
15:09:21 would be a 30 percent reduction, that was speculation,
15:09:24 that was a hypothesis; correct?
15:09:26 **A.** That's what she said. That's all I know.
15:09:28 **Q.** There is no data to support that; correct?
15:09:30 **A.** No. She was saying this is what it would
15:09:32 look like in her opinion.
15:09:33 **Q.** And that was a hypothesis; correct?
15:09:35 **A.** Correct.
15:09:35 **Q.** And there are many times that hypotheses are
15:09:38 wrong; correct?





15:09:39 **A.** Sometimes that happens.
15:09:40 **Q.** And that's why you do the study; correct?
15:09:42 **A.** Yes.
15:09:44 **Q.** Okay. So you agree that she admits that the
15:09:50 reduction of infection is going to be a lot less than
15:09:53 threefold, and it's her hypothesis that if the study
15:09:58 was done now it would be about 30 percent reduction
15:10:00 for colorectal surgeries.
15:10:02 MR. COREY GORDON: Object to the form of
15:10:03 the question, lack of foundation.
15:10:05 **A.** I mean, what I would say is, you know, that
15:10:07 study done, what, 20 years ago or so, in the meantime
15:10:12 a whole lot of other changes, we'll just mention
15:10:15 Darouiche and the -- and the antiseptic. And one of
15:10:19 the concepts that I think goes on as you look at more
15:10:22 recent studies, which reflects on your question, is
15:10:27 what's the modifiable, residual modifiable effect you
15:10:32 can have when you start adding all things that cut
15:10:35 down the infection rate. It's awful hard to show,
15:10:39 when you're moving away from that, if you have three
15:10:42 or four or five, you know, improvements in outcome,
15:10:47 then you have less proportion of infections you can
15:10:50 impact with a new process or a new product.
15:10:56 Am I making sense, or?
15:10:57 **Q.** Wel, yeah, you're making...





15:10:58 Let me ask you a question. If a patient
15:11:02 only used warm blankets during a total hip or total
15:11:06 knee arthroplasty, do you know whether or not the
15:11:09 patient would become hypothermic?
15:11:12 **A.** No, I don't know that. I don't know what
15:11:12 the --
15:11:12 **Q.** So --
15:11:14 **A.** -- data show.
15:11:16 **Q.** -- sitting here today, you don't know
15:11:17 whether or not just using warm blankets is just as
15:11:21 efficacious as the forced-air warming.
15:11:23 **A.** I thought there were studies that showed it
15:11:25 didn't work as well. Can't cite them right now, but I
15:11:30 have read that somewhere.
15:11:31 **Q.** You haven't --
15:11:32 Did you ever look at the Dr. Sessler study
15:11:35 of 2015 that compared just blankets to forced-air
15:11:38 warming?
15:11:39 **A.** No. I don't know that one.
15:11:56 **Q.** And in fact you're familiar with the study
15:11:59 that looked at the data out of Hopkins that showed no
15:12:04 reduction in periprosthetic joint infections between
15:12:09 patients that had thermoregulation and patients that
15:12:14 didn't have thermoregulation.
15:12:15 **A.** You're talking about the first study in





15:12:17 my -- in my chart of the cohorts?
15:12:19 **Q.** I'm not sure, but do you recall the Hopkins
15:12:22 study that looked at the Hopkins data?
15:12:24 **A.** Yeah, I think -- Let me just -- I have that
15:12:27 in the chart of cohorts that we just looked at. Here
15:12:33 we go. So page 8.
15:12:35 What I'm asking you, I guess, is are you
15:12:37 referring to the study number 1 at the top? Hopkins
15:12:45 uses a WarmTouch forced-air warming, and that was a
15:12:50 big study, you know, 46,000 plus, it's a cohort.
15:12:55 Amazing low percent that got hypothermic.
15:12:59 **Q.** Is this the Brown study?
15:13:01 **A.** Forgot the name of the first author. But
15:13:10 the lead author is -- was an anesthesiologist I think,
15:13:14 the other ones who did that.
15:13:32 **Q.** This is the Scott study; correct?
15:13:33 **A.** I think it's the Scott study. That's right,
15:13:35 yeah.
15:13:35 **Q.** Okay. And if you look at the Scott study --
15:13:51 Do you know what the SCIP protocols are?
15:13:54 **A.** Yeah. I have an idea, yeah.
15:13:55 **Q.** So for wound infection, the -- when a --
15:14:00 when the patients were not com -- SCIP non-compliant
15:14:04 you had 3.6 percent of wound infection, and when they
15:14:07 were SCIP compliant they had 3.8 percent wound

infection.

So how do you get an SSI of -- a risk ratio of .86 for wound infe -- for surgical-site infection?

**A.** I don't remember how I got that, but it was clearly not significant.

**Q.** Okay. So you agree with me that even current studies show that there is no benefit with forced-air warming with respect to surgical-site infections.

**A.** Especially current studies, because of all the management that has gone on beforehand to introduce controls of the residual proportion of infections that you can mod -- you know, modulate.

**Q.** So you would agree with Andrea Kurz, then, that in -- in today's world, okay, --

**A.** Umm-hmm?

**Q.** -- that there's no scientific evidence that indicates that forced-air warming reduces the incident of surgical-site infections.

**A.** No, I won't --

MR. COREY GORDON: Object to the form of the question, and misstates the evidence.

**A.** No, I won't agree with that.

What I'm saying is she was saying that, look, you know, going forward with all the changes





going on we might only see 30 percent instead of 67 percent reduction. That's what I recall, and that's what I cited in my report.

**Q.** But you also cited Scott --

**A.** Yeah.

**Q.** -- that showed that patients that were SCIP non-compliant had a lower infection rate than patients that were SCIP compliant.

**A.** Well if you look at all infections, that was statistically significant, all -- all infections. The surgical site he couldn't show a difference.

**Q.** Okay. We're not looking at all infections here, doctor.

**A.** Yeah, okay.

**Q.** We're looking at surgical-site infections.

**A.** Perfect.

**Q.** Which is a wound infection; correct?

**A.** Yes.

**Q.** Okay. And in the Scott study SCIP non-compliant had a lower infection rate than SCIP compliant; correct?

**A.** You mean a non -- nonsignificant --

**Q.** It's nonsignificant, but it was still -- it was still lower.

**A.** Fine.





**Q.** Okay. I mean, you're right, it is nonsignificant --

**A.** Yeah.

**Q.** -- because the p value's .7811.

**A.** Yeah. Not at all.

**Q.** The p value's very high.

**A.** Yeah.

**Q.** So that would indicate to a scientist, such as yourself, that there's no difference between -- between warming and non-warming.

**A.** True.

**Q.** Okay.

MR. COREY GORDON: Object to the form of the question.

**Q.** Now you spent a considerable amount of time going over comorbidities.

**A.** Yeah.

**Q.** Okay. Can we just agree that the comorbidities will be case specific depending on the patient?

MR. COREY GORDON: Object to the form of the question.

**A.** So if you're asking can I predict the infection rate above or below the average as a result of incorporating comorbidities, yes. Is that what





you're asking?

**Q.** I mean, for example, you talk about diabetes and obesity, --

**A.** Yeah.

**Q.** -- other things.

But you would agree with me that that discussion might be more appropriate when we actually know what patient we're talking about; correct?

MR. COREY GORDON: Object to the form of the question.

MR. ASSAAD: Basis?

MR. COREY GORDON: Appropriate to what? Appropriate to his discussion of why McGovern is not effective? No. The word "appropriate" is -- is completely vague and meaningless.

MR. ASSAAD: Why are you yelling to me, Corey?

MR. COREY GORDON: I'm not yelling. I'm -- You're detecting an exasperated tone in my voice, but I'm not yelling.

MR. ASSAAD: Are you picking up that stick to hit me?

MR. COREY GORDON: Not yet.

(Laughter.)

MR. GOSS: Let me tell you, it hurts when

15:18:54 that thing comes down.
15:18:56 (Laughter.)
15:18:56 BY MR. ASSAAD:
15:19:30 **Q.** Are you aware of articles that discuss that
15:19:32 the incidence of periprosthetic joint infections are
15:19:34 going to increase over the next twenty -- up to 2030?
15:19:39 MR. COREY GORDON: Object to the form of
15:19:40 the question.
15:19:40 **A.** Yeah, related to the increased number of
15:19:41 people who are undergoing the procedures, so.
15:19:44 **Q.** When we talk about incidence, I'm talking
15:19:46 about the percentage.
15:19:48 **A.** Percent?
15:19:48 **Q.** Do you recall an article that indicated by
15:19:51 2030 the -- the incident of periprosthetic joint
15:19:57 infections will be as high as 6 percent?
15:19:59 **A.** I'm not aware of that at all.
15:20:42 **Q.** You would agree with me that being diabetic
15:20:47 is not a cause of the infection.
15:20:51 MR. COREY GORDON: Object to the form of
15:20:52 the question.
15:20:53 **A.** I don't agree with that at all. My view of
15:20:56 infections, surgical-site infections is that they're
15:21:01 multifactorial and the comorbidities, for example, are
15:21:05 a -- one factor that can certainly change the baseline





15:21:10 rate if you're not having those comorbidities. So I
15:21:14 look at all the risk factors as, if you will, risk
15:21:20 factors and causes. So if you said to me, I have
15:21:23 twins, one of them is -- you know, exactly the same
15:21:28 genetics, same surgeon, same operation, everything the
15:21:31 same except one's an obese diabetic, and that patient
15:21:36 gets an infection post-op, of course the diabetes and
15:21:41 the obesity contributed to that person's increased
15:21:44 risk of infection.
15:21:47 **Q.** Doesn't that go to susceptibility?
15:21:54 **A.** What I know it goes to is -- at least in
15:21:58 terms of diabetes and obesity, is a change in the
15:22:02 microbiome. Is that what you mean by
15:22:05 "susceptibility"?
15:22:05 **Q.** So you think in that -- And -- Okay.
15:22:10 I want to make sure I understand you. You
15:22:12 think obesity and diabetes has an effect on the human
15:22:15 microbiome.
15:22:15 **A.** It does, and I've cite -- several studies
15:22:18 that I've cited.
15:22:19 **Q.** Okay. And therefore what type of effect;
15:22:25 does it increase the -- the number of bacteria on the
15:22:29 skin?
15:22:29 MR. COREY GORDON: Object to the form of
15:22:30 the question.





15:22:30 **A.** Increases for sure the number of people who
15:22:33 are nasal carriers of Staph aureus, and by definition
15:22:39 those people are more susceptible to infections.
15:22:41 There may be other things as well, but that's -- the
15:22:43 study of the microbiome is pretty young still, but
15:22:46 it's a remarkable thing that we have several studies
15:22:49 showing that.
15:22:49 **Q.** But you still -- you agree with me that the
15:22:51 fact that --
15:22:54 You still need the bacteria to cause the
15:22:56 infection; correct?
15:22:58 **A.** Bacteria are necessary, not sufficient.
15:23:02 **Q.** You can't have an infection without the
15:23:03 bacteria; correct?
15:23:04 **A.** That's true.
15:23:05 **Q.** Okay. And you are just saying that a person
15:23:09 that is obese might be more likely to be a Staph
15:23:15 aureus carrier or an MRS carrier.
15:23:18 **A.** That's for sure, and I know that person's at
15:23:20 higher risk when you look at the epidemiologic
15:23:24 studies, which I've cited, for getting a surgical-site
15:23:27 infection.
15:23:28 **Q.** I understand that.
15:23:28 But my point is that makes them more
15:23:33 susceptible, not that -- I mean --





15:23:36 The only thing I know that causes a
15:23:38 periprosthetic joint infection is a bacteria; correct?
15:23:40 **A.** That's always there.
15:23:41 **Q.** Okay. The fact that I am -- someone's obese
15:23:44 is not going to spontaneously have an infection
15:23:47 without a bacteria; correct?
15:23:49 **A.** Correct.
15:23:49 **Q.** Okay. It is the bacteria that causes the
15:23:53 infection, and it is the host that may be susceptible
15:23:58 more or less than the average human and may allow the
15:24:06 infection to progress.
15:24:07 MR. COREY GORDON: Object to the form of
15:24:08 the question.
15:24:08 **A.** You and I are going to disagree. I mean, I
15:24:11 think that risk factors are, by definition, causal,
15:24:15 and -- that's why I tried to give you the twins, one
15:24:20 was a diabetic obese, and without that that person,
15:24:24 the twin, didn't get an infection. You're asking a
15:24:27 little bit about mechanisms, which aren't fully worked
15:24:30 out.
15:24:31 **Q.** Well the one that's diabetic obese compared
15:24:33 to the regular twin, okay, the diabetic obese still
15:24:51 would have to have a bacteria that would get into the
15:24:53 joint area during the operation to cause an infection;
15:24:55 correct?

15:24:56 **A.** Yeah. I mean --
15:24:57 **Q.** And the same thing with a person that's
15:24:59 skinny; correct?
15:25:00 **A.** That's correct.
15:25:00 **Q.** Unless, let's assume it's the same amount of
15:25:03 bacteria, say it's a thousand CFUs or 10,000 CFUs,
15:25:08 okay? My understanding, and see if we could agree,
15:25:10 that the diabetic obese patient is more prone to --
15:25:14 for the -- for the CFUs to -- to -- like -- more
15:25:20 likely to become infected because that person is obese
15:25:23 and a diabetic as compared to the healthy person.
15:25:28 MR. COREY GORDON: Object to the form.
15:25:30 **Q.** Do you understand what I'm saying?
15:25:31 **A.** Not really, no.
15:25:36 **Q.** Okay. You still need the bacteria to land
15:25:37 on the -- the diabetic and obese person; correct?
15:25:42 **A.** Correct.
15:25:42 **Q.** If no bacteria lands on the joint during the
15:25:44 operation of a diabetic obese patient, that patient,
15:25:49 more likely than not, is not going to have an
15:25:50 infection; correct?
15:25:51 **A.** Yes.
15:25:51 MR. COREY GORDON: Object to the form of
15:25:52 the question.
15:25:53 **Q.** Correct?





15:25:54 **A.** Yes.
15:25:54 **Q.** And in fact it would be impossible, without
15:25:56 bacteria, for that person to have an infection;
15:25:58 correct?
15:25:58 **A.** Need the bacteria.
15:25:59 **Q.** Huh?
15:26:00 **A.** Need the bacteria.
15:26:01 **Q.** You need the bacteria.
15:26:02 Whether or not you are obese, diabetic,
15:26:05 immunosuppressed and whatever type of comorbidity
15:26:10 there is, you need the bacteria.
15:26:11 **A.** Yes.
15:26:12 **Q.** Okay. You could be immunosuppressed and go
15:26:29 through a total hip and total knee arthroplasty, and
15:26:32 as long as no bacteria lands in the joint area you're
15:26:34 not going to get an infection; correct?
15:26:36 **A.** I think that's true.
15:26:38 **Q.** Same thing with a diabetic; correct?
15:26:40 **A.** Yes.
15:26:41 **Q.** Same thing with an obese person; correct?
15:26:42 **A.** Yes.
15:26:43 **Q.** Okay. You need the bacteria to get to the
15:26:45 joint; correct?
15:26:46 **A.** You do.
15:26:47 **Q.** Okay. Go to page 13.





15:27:25 **A.** Sure.
15:27:45 **Q.** On the third paragraph from the bottom where
15:27:47 it says: "Thus, substantial rises in comorbidities"?
15:27:51 Do you see that?
15:27:52 **A.** I do.
15:27:53 **Q.** Okay. The last sentence you say, "...it has
15:27:56 been reported that surgical site infection rates have
15:27:58 fallen over time during the use of Bair Hugger."
15:28:00 Correct? I read that correctly?
15:28:01 **A.** Yeah.
15:28:02 **Q.** You're talking about superficial wound
15:28:04 infections; correct?
15:28:05 **A.** They're probably mixed.
15:28:07 **Q.** Well we just said there was no study on
15:28:09 periprosthetic joint infections.
15:28:10 MR. COREY GORDON: Object to the form of
15:28:12 the question.
15:28:14 **A.** Yeah. I don't know that they didn't count
15:28:21 -- I mean CDC has rates for hips and --
15:28:21 (Interruption by the reporter.)
15:28:25 **A.** -- has rates of infection for total hip
15:28:28 placement, total knee replacement from their national
15:28:31 cohort. And what I cited in the report was if you
15:28:35 look at the trends over time, and they corrected for
15:28:39 some of the comorbidities the best they could, they've





15:28:42 actually shown a decline, something like 27 to 43
15:28:45 percent depending on one's hips, one's knees.
15:28:49 **Q.** Are you aware of the -- the Parvizi studies
15:28:53 regarding the economic burden of periprosthetic joint
15:28:55 infections?
15:28:56 **A.** I think so. I don't remember exactly what
15:28:57 number he came up with, but.
15:29:01 **Q.** Well you know that Dr. Parvizi has looked at
15:29:04 this issue; correct?
15:29:05 **A.** Yeah.
15:29:05 MR. COREY GORDON: Object to the form of
15:29:07 the question.
15:29:07 MR. ASSAAD: Basis?
15:29:08 MR. COREY GORDON: What is "this issue"?
15:29:10 You've just -- You've had a whole line of questions
15:29:12 where you're asking him about the trends, and then
15:29:13 you switch gears and then you say he's -- Parvizi has
15:29:18 looked at "this issue."
15:29:21 BY MR. ASSAAD:
15:29:25 **Q.** Doctor, you knew what I was talking about
15:29:27 when I said "this issue"; correct?
15:29:29 **A.** I did.
15:29:29 MR. COREY GORDON: Object to the form of
15:29:30 the question, lack of foundation.
15:29:31 **Q.** We were talking about infection rates;

15:29:33 correct?
15:29:34 **A.** Yes.
15:29:34 **Q.** And Dr. Parvizi has looked at infection
15:29:37 rates over time.
15:29:37 **A.** And he showed, yeah, a fall.
15:29:40 **Q.** You believe he saw -- he's seen a fall?
15:29:42 **A.** That's what he said.
15:29:43 **Q.** When did he say this?
15:29:44 **A.** In a paper.
15:29:45 **Q.** Okay.
15:29:46 **A.** Can we pull it out?
15:29:48 **Q.** Are you familiar with a paper titled
15:30:02 *Economic Burden of Periprosthetic Joint Infections in*
15:30:05 *the United States*, authored by Steven Kurtz, Evan Lau,
15:30:10 Heather Watson, Jordan Schmier and Javad Parvizi?
15:30:15 **A.** I don't think I -- I don't remember it.
15:30:17 That's -- I may have read it, I don't remember.
15:30:19 **Q.** Published in 2011?
15:30:20 **A.** Yeah, I don't remember it.
15:30:23 **Q.** I'm sorry. 2012.
15:30:27 **A.** I don't remember it.
15:30:40 **Q.** What Parvizi article are you referring to
15:30:43 that says he reduced -- reduction of infection?
15:30:46 **A.** Let me see if I can find it. (Witness
15:30:56 reviewing exhibit.) Oh, I was thinking -- it's the





15:30:59 Rasouli paper, but I was thinking he was a co-author.
15:31:03 **Q.** What page are you looking at, sir?
15:31:05 **A.** So page 13.
15:31:06 **Q.** What paragraph?
15:31:08 **A.** It's Roman numeral vi. And if Parvizi
15:31:24 wasn't part of that study then that's my mistake, but
15:31:29 Rasouli is actually the first author.
15:31:41 **Q.** Mohammad Rasouli?
15:31:43 **A.** I think that's right.
15:31:49 **Q.** Okay. Did you look at what ICD-9 codes they
15:31:56 looked at in formulating this opinion?
15:31:58 **A.** I saw them, but I don't memorize those or
15:32:02 anything, yeah.
15:32:02 **Q.** Okay. You could look them up, though;
15:32:03 correct?
15:32:04 **A.** I could have, yeah.
15:32:05 **Q.** Okay. And you didn't do that in this case;
15:32:06 correct?
15:32:07 **A.** No.
15:32:07 **Q.** Okay. And if you look at --
15:32:23 What do you think the infection rate is for
15:32:24 primary total hip or total knee infections in the
15:32:28 United States currently?
15:32:29 **A.** Currently?
15:32:30 **Q.** Uh-huh.





15:32:30 **A.** My estimate is probably one percent or so.
15:32:33 **Q.** Okay. So if that's the case, and I think
15:32:36 that might be acceptable, Rasouli is only showing .2
15:32:42 percent infection rates for primary hip or primary
15:32:45 knee. That sounds very low; doesn't it?
15:32:47 **A.** It does seem --
15:32:48 MR. COREY GORDON: Object to the form of
15:32:49 the question.
15:32:49 **Q.** That seems very low, doesn't it, sir?
15:32:51 **A.** It seems low.
15:32:52 **Q.** Okay. Would that cause you any concern to
15:32:54 see what -- to check to see how he calculated his
15:32:55 infection rate?
15:32:56 **A.** It's one paper.
15:32:57 **Q.** Okay. And there's two papers by Dr. Parvizi
15:33:00 that you have not looked at; correct?
15:33:03 MR. COREY GORDON: Object to the form of
15:33:03 the question.
15:33:04 **A.** Don't remember which ones I didn't look at.
15:33:06 Are they the ones you were talking about earlier?
15:33:07 **Q.** Yes.
15:33:07 **A.** Yeah.
15:33:07 **Q.** The economic burden ones.
15:33:09 **A.** Yeah, I don't remember that.
15:33:10 **Q.** Okay. You also have an opinion that the





15:34:24 number of health professionals in an operating room
15:34:27 had no significant influence on bacterial counts in
15:34:30 the operating room; correct?
15:34:32 **A.** What page you looking at?
15:34:33 **Q.** 16.
15:34:39 **A.** Sixteen?
15:34:40 **Q.** Yeah.
15:34:42 **A.** Under "Summary"?
15:34:47 **Q.** I'm sorry. I'm looking at something else.
15:34:48 I apologize. Withdraw the question.
15:34:50 Okay. Let's go to page 19.
15:35:15 **A.** Yeah.
15:35:17 **Q.** This talks about your hierarchy of Bair
15:35:19 Hugger studies; correct?
15:35:21 **A.** Sure.
15:35:21 **Q.** Okay. Can we agree, with respect to whether
15:35:27 or not the Bair Hugger increases the bacterial load
15:35:33 over the surgical site, that the Melling article is
15:35:38 irrelevant?
15:35:40 MR. COREY GORDON: Object to the form of
15:35:42 the question.
15:35:42 **A.** No, I don't know that I would agree. I
15:35:44 mean, it adds data.
15:35:45 **Q.** Well the Bair Hugger's u -- we're talking
15:35:47 about the Bair Hugger being used perioperatively;

15:35:50 correct?
15:35:50 **A.** Yeah.
15:35:50 **Q.** And the Melling was pre-warming; correct?
15:35:52 **A.** That's correct.
15:35:53 **Q.** So whether or not -- I mean we're not
15:35:56 looking at pre-warming here, we're looking at
15:36:01 perioperative warming. You understand that; correct?
15:36:04 **A.** I do, and I've cited the paper that says
15:36:07 warming and pre-warming might last up to a couple of
15:36:09 hours.
15:36:10 **Q.** But we're talking about --
15:36:11 Do you understand plaintiffs' allegations
15:36:12 that the Bair Hugger increases the bacterial load over
15:36:16 the surgical site?
15:36:19 **A.** What I remember that you asked me the
15:36:21 hypothesis that I thought they had was that it created
15:36:25 a kind of a dust storm from the floor that came up
15:36:28 over the surgical site, yes.
15:36:30 **Q.** Well let's -- Yeah. So -- So there has to
15:36:33 be a surgical site; correct?
15:36:35 **A.** Yeah.
15:36:36 **Q.** Okay. There's no surgical site or wound
15:36:38 during pre-warming; correct?
15:36:40 **A.** That's true.
15:36:41 **Q.** So with respect to whether or not the Bair





15:36:43 Hugger increases the risk of surgical-site infection,
15:36:46 you have to look at studies that deal with the Bair
15:36:49 Hugger being used during perioperative warming;
15:36:52 correct?
15:36:53 **A.** What I would say is if you have pre-warming
15:36:57 and the body stays warm and you avoid all the
15:37:00 vasoconstriction that cooling does, that's a good
15:37:03 thing. Is that -- So maybe I'm not getting close
15:37:05 enough here.
15:37:07 **Q.** Well plaintiffs' allegation for -- just keep
15:37:10 it simple. The Bair Hugger is being used and it
15:37:13 causes increased bacteria over the wound.
15:37:18 **A.** Umm-hmm.
15:37:18 **Q.** Okay? You understand that.
15:37:19 **A.** Yeah.
15:37:20 **Q.** Okay. Melling doesn't deal with
15:37:23 perioperative warming; correct?
15:37:25 **A.** He deals with pre-warming.
15:37:26 **Q.** Okay. So that's a different situation of
15:37:29 what plaintiffs' allegations are in this case.
15:37:32 **A.** Might be technically. I was just trying to
15:37:36 say that the physiology is the same, that's all.
15:37:42 **Q.** Have you looked at the stu -- all the
15:37:48 studies under the Biological Plausibility Studies on
15:37:52 page 20?





15:37:53 **A.** Yeah. I have a table on that somewhere that
15:37:55 might make it easier. Maybe it was earlier. (Witness
15:38:05 reviewing exhibit.) Here we go.
15:38:08 **Q.** On page 14?
15:38:09 **A.** Page 14 and 15, yeah.
15:38:11 MR. COREY GORDON: 14 to 15, partly. Oguz
15:38:18 isn't in that table, you discuss that elsewhere.
15:38:23 MR. ASSAAD: Do you want to testify some
15:38:25 more, Mr. -- Mr. Gordon?
15:38:26 MR. COREY GORDON: I'm just trying to --
15:38:28 **Q.** So doctor -- doctor --
15:38:30 MR. COREY GORDON: Go back to 20 and have
15:38:31 him talk about it from there rather than the table.
15:38:36 BY MR. ASSAAD:
15:38:36 **Q.** Doctor, do you know what device was used in
15:38:39 the Zink study, which Bair Hugger device?
15:38:42 **A.** I don't -- No. Don't remember.
15:38:43 **Q.** So you don't know what -- what the airflow
15:38:45 of that device was?
15:38:46 **A.** No.
15:38:46 **Q.** Okay. Don't you think it'd be relevant to
15:38:49 determine whether that study applies to the device
15:38:51 that's being used in this litiga -- being -- in this
15:38:54 litigation?
15:38:55 **A.** Told you I don't know what device they had





15:38:56 there.
15:38:56 **Q.** That wasn't my question, sir.
15:38:56 **A.** Yeah.
15:38:58 **Q.** Don't you think knowing what device was
15:38:59 studied is relevant to determine whether that article
15:39:02 is relevant to the device that's being used in this
15:39:06 litigation?
15:39:07 **A.** Could --
15:39:07 MR. COREY GORDON: Object to the form of
15:39:08 the question.
15:39:08 **A.** Yeah, it might be. I don't know.
15:39:10 **Q.** It may be; right?
15:39:11 **A.** Yeah. Yeah. Might be.
15:39:12 **Q.** And you don't know today what device was
15:39:14 used; do you?
15:39:15 **A.** Yeah, I don't.
15:39:15 **Q.** Okay. The Hall -- The Hall is a poster;
15:39:17 correct? A.C. Hall?
15:39:18 **A.** It was.
15:39:19 **Q.** It's not peer reviewed; correct?
15:39:21 **A.** I'm not sure it wasn't peer reviewed, but it
15:39:25 wasn't a peer-reviewed full article.
15:39:28 **Q.** Okay. Well --
15:39:28 (Interruption by the reporter.)
15:39:29 **Q.** And that was in 1991; correct? December 9th

15:39:33 --
15:39:33 **A.** Yes. Yes, yes.
15:39:35 **Q.** Do you know what device was used in that
15:39:37 article?
15:39:37 **A.** No, I don't.
15:39:38 **Q.** Okay. So it might be a different device
15:39:41 that is at issue in this litigation; correct?
15:39:43 **A.** I don't know. Might be.
15:39:44 **Q.** Okay. And that would be relevant.
15:39:46 **A.** Might be.
15:39:46 **Q.** Okay. The Huang article, do you know what
15:39:52 device was used in that case?
15:39:54 **A.** No.
15:39:56 **Q.** And do you have any criticisms of these
15:39:58 articles?
15:40:00 **A.** They're small studies, they're not always,
15:40:08 you know, controlled studies. Well they are, I guess.
15:40:11 Well one of them wasn't, the Dirkes study. But mostly
15:40:16 I think they're just small studies that try to look
15:40:22 at, I think, a relevant question.
15:40:26 **Q.** By the way, does it -- do you take into
15:40:28 consideration who funds the studies?
15:40:30 **A.** You have to look at that.
15:40:31 **Q.** Okay. But just because a person funds a
15:40:34 study doesn't mean the study's not a good study;





15:40:36 correct?
15:40:37 **A.** I would say that's true.
15:40:38 **Q.** Okay. Otherwise, I mean, you would
15:40:42 eliminate most of the studies that are out there
15:40:44 because they're usually financed by a corporation.
15:40:46 **A.** Well I've done a lot of studies funded by
15:40:49 industry, and as I told you, many of them turn out to
15:40:51 be nothing, and I wrote the paper up and kind of read
15:40:55 'em and weep.
15:40:58 **Q.** And usually good studies -- or corporations,
15:41:01 when they fund a study, should not be involved in the
15:41:06 study; correct?
15:41:09 **A.** Yeah. When I've done studies myself, they
15:41:12 haven't been involved.
15:41:13 **Q.** They should have no editorial review of the
15:41:17 studies.
15:41:17 **A.** Actually, as a courtesy after each of those
15:41:19 studies, most of us would give industry some time
15:41:24 period, like 30 days to look at it. They can make
15:41:28 comments, but we make the final decision.
15:41:30 **Q.** Okay. But you wouldn't give them carte
15:41:34 blanche to make any changes to the --
15:41:36 **A.** Oh, no.
15:41:36 **Q.** Okay. That would be unethical; wouldn't it?
15:41:36 **A.** That'd be --





15:41:41 Yes.
15:41:41 **Q.** Okay. I mean, look at the Zink study. That
15:41:54 only had eight volunteers; correct?
15:41:56 **A.** That's true.
15:41:57 **Q.** That's a very small study; correct?
15:41:59 **A.** That's true.
15:41:59 **Q.** Okay. If -- When we're looking at bacterial
15:42:03 load with airborne contamination, that is a very
15:42:10 underpowered study; correct?
15:42:11 **A.** It's under --
15:42:12 MR. COREY GORDON: Object to the form of
15:42:13 the question.
15:42:13 **Q.** Very underpowered; correct?
15:42:15 **A.** It's underpowered.
15:42:16 **Q.** Okay. And in fact do you know whether or
15:42:19 not -- I mean, you agree with me, as we stated before,
15:42:22 that the amount of people in the operating room have
15:42:24 an effect on the bacterial load in the operating room;
15:42:26 correct?
15:42:27 **A.** I think they do.
15:42:28 **Q.** Okay. Do you know how many people were in
15:42:31 the operating room when they did this study?
15:42:32 **A.** Don't remember, no.
15:42:33 **Q.** Okay. Because it would be a big difference
15:42:37 if there was only one person, the patient, as compared





15:42:40 to the patient and six or seven or eight people in the
15:42:42 operating room; correct?
15:42:43 **A.** I think there would be a difference.
15:42:44 **Q.** Okay. And when you do a study you want to
15:42:49 imitate the study as much as possible to what really
15:42:52 happens in real life; correct?
15:42:53 **A.** Yeah, always. Yeah.
15:42:55 **Q.** Okay. Otherwise, I mean, you might get
15:43:00 results, but it's hard to apply those -- the results
15:43:03 to make decisions with respect to clinical care if the
15:43:07 scenarios are not similar; correct?
15:43:10 **A.** It's easier to make results if you have a --
15:43:13 the closer it is to what goes on, no question. But I
15:43:16 wouldn't throw the studies out, if that's part of the
15:43:19 question.
15:43:21 **Q.** Well I don't see you criticizing any of
15:43:23 these studies in here that's saying that they're
15:43:27 underpowered.
15:43:27 **A.** I didn't say that. I just told you they're
15:43:29 underpowered and they're small studies.
15:43:31 **Q.** I understand. And you criticized McGovern
15:43:33 and you criticized all these other studies, but you
15:43:36 don't criticize the studies that 3M relies upon.
15:43:36 MR. COREY GORDON: Object --
15:43:38 **Q.** Why is that, sir?

15:43:40 MR. COREY GORDON: Object to the form of the question.
15:43:40 **Q.** Why is that, sir?
15:43:40 MR. COREY GORDON: Object to the form of the question.
15:43:43 **A.** I'm very happy to talk about this, you know, but.
15:43:44 **Q.** We can talk about it all you want, but I'm saying why in your report you did not criticize or discuss any of the weaknesses in the studies that 3M rely upon.
15:43:47 MR. COREY GORDON: Object to the form of the question.
15:43:49 **A.** Yeah, I -- I think I took these studies, this is what I found, and collectively they showed nothing in terms of colony-forming units increasing as a result of the Bair Hugger.
15:43:52 **Q.** But you would criticize Zink, Hall, Huang, Dirkes, and Moretti as being underpowered, wouldn't you?
15:43:55 **A.** So these are small studies, that's true. That's the best data we have.
15:43:56 **Q.** Did you criticize them at all and say they're underpowered in the paper?
15:43:57 **A.** I didn't do that.
15:43:57
15:44:00
15:44:03
15:44:08
15:44:09
15:44:14
15:44:17
15:44:17
15:44:19
15:44:21
15:44:23
15:44:24





15:44:25 **Q.** That's not being objective, sir, is it?
15:44:27 **A.** I think I --
15:44:27 MR. COREY GORDON: Object to the form of the question.
15:44:28 **Q.** That's not being objective, sir, is it?
15:44:28 **A.** I think I'm fine with this.
15:44:29 **Q.** Oh, you're fine with that, okay.
15:44:31 **A.** Yeah.
15:44:32 **Q.** That wasn't my question.
15:44:33 Is that being objective?
15:44:33 MR. COREY GORDON: Object to the form of the question. Move to strike counsel's snide comment.
15:44:34
15:44:36
15:44:39
15:44:52 **Q.** You cite Avidan; correct?
15:44:55 **A.** Yes. On the next page, 15.
15:44:57 **Q.** That was a small study as well; correct?
15:44:59 **A.** It was a small study.
15:45:00 **Q.** Okay. And you don't know what device was used in that case; do you?
15:45:04 **A.** No, I don't.
15:45:05 **Q.** And Occhipinti, you don't know what device was used in that case; correct?
15:45:05
15:45:09
15:45:10 **A.** Don't know what device.
15:45:11 **Q.** And that dealt with surgical drapes; correct?
15:45:13





15:45:14 **A.** It's what?
15:45:14 **Q.** That dealt with surgical drapes.
15:45:17 **A.** Yes.
15:45:19 **Q.** Okay. Did you read the letter to the editor by Farhad Memarzadeh in the Moretti case?
15:45:20 **A.** No.
15:45:24 **Q.** Any criticism of Avidan besides it's -- it's a small study?
15:45:32 **A.** Well, I mean, one of the things you would say is when the plates were directly in the airstream 16 be -- inches below the end of the hose you could argue that you're not really sure what was coming out was from only the hose or the air below. That would be one criticism.
15:45:35
15:45:42
15:45:44
15:45:48
15:45:51
15:45:56
15:45:58
15:46:00 **Q.** Okay. You didn't put that in your report; did you?
15:46:02 **A.** No, I didn't.
15:46:02 **Q.** Okay. You cite to the Oguz study; correct? O-G-U-Z.
15:46:05
15:46:26
15:46:26 **A.** Yes. Yes.
15:46:28 **Q.** Any criticism of that study?
15:46:29 **A.** It was pretty good. He randomized people, there were 80 orthopedic patients, and he looked at the influence of either device on the CFUs and found none.
15:46:32
15:46:37
15:46:42





15:46:49 **Q.** "Found none"?
15:46:50 **A.** Huh?
15:46:50 **Q.** "Found none"?
15:46:51 **A.** No influence.
15:46:52 **Q.** So you wouldn't agree with me that if you looked at the comparison between the Bair Hugger and the HotDog in the Oguz study that there was an increase in bacterial load using the Bair Hugger over the HotDog?
15:46:54
15:46:56
15:47:00
15:47:02
15:47:03 MR. COREY GORDON: Object to the form of the question, mischaracterizes the evidence.
15:47:05
15:47:07 **A.** I mean, what he found at the end using his model, multivariate model, and asked the question, does the individual device actually influence the counts, and he couldn't find it.
15:47:09
15:47:13
15:47:18
15:47:27 (Wenzel Exhibit 11 marked for identification.)
15:47:27
15:47:27 BY MR. ASSAAD:
15:47:35 **Q.** What's been marked as Exhibit 11 is the Oguz article --
15:47:38
15:47:41 What's been marked as Exhibit 11 is the Oguz article that was provided to us by Dr. Wenzel today, August 4, 2017, according to a subpoena that was issued to be produced to us by June 21st, but we got it today.
15:47:45
15:47:49
15:47:54
15:47:59

15:47:59 And it's underlined by Dr. Oguz; is that
15:48:02 correct?
15:48:04 **A.** Underlined by me?
15:48:05 **Q.** Yes.
15:48:05 **A.** Yeah.
15:48:06 **Q.** Okay. Can I have that back, please?
15:48:07 **A.** Sure. (Handing.)
15:48:08 **Q.** Now what you didn't underline here was the
15:48:13 statement by the authors that, this study may
15:48:16 obviously not be generalized for an overall safety
15:48:19 statement on forced-air warming, and is primarily
15:48:23 applicable in the particular surgical setup.
15:48:26 You didn't underline that; did you?
15:48:27 **A.** No.
15:48:28 **Q.** Okay. That's a pretty important statement
15:48:30 by the authors; isn't it?
15:48:31 MR. COREY GORDON: Object to the form of
15:48:32 the question, lack of foundation.
15:48:34 **A.** Where am I looking here?
15:48:38 **Q.** (Indicating.) Right after you stopped
15:48:40 underlining up here.
15:48:41 **A.** Right there? (Witness reviewing exhibit.)
15:48:49 So you're saying "only the maximum number of health
15:48:52 professionals" --
15:48:53 **Q.** No. Over here, sir. Right after this





15:48:55 underline here. [Indicating.]
15:48:56 **A.** Oh, this one. Okay. (Witness reviewing
15:49:05 exhibit.)
15:49:05 It might not. So I think that -- I think
15:49:11 good authors will try to look and give their own
15:49:14 critique of potential shortcomings.
15:49:17 **Q.** Okay. Now let's look at the table
15:49:19 underneath there that looked at the multivariate
15:49:23 analysis.
15:49:25 Do you agree with me for four out of the six
15:49:29 plates that there is a higher incident of bacteria
15:49:34 when forced-air warming was used as compared to when
15:49:37 forced-air warming was not used, or when the HotDog
15:49:39 was used?
15:49:42 **A.** Where is this?
15:49:43 **Q.** Table 2.
15:49:44 **A.** Oh, I'm sorry. It's these?
15:49:45 **Q.** Yeah. The second line down.
15:49:47 **A.** Okay. (Witness reviewing exhibit.) So what
15:50:07 are you -- Make sure that I know what you're looking
15:50:09 -- what numbers.
15:50:10 **Q.** Let me read it out loud for you.
15:50:11 **A.** Yeah. Go ahead.
15:50:12 **Q.** Table 2 is the results of a multivariate
15:50:15 analysis of factors; correct?





15:50:16 **A.** Yeah. Yeah.
15:50:16 **Q.** And that's what you were talking about;
15:50:17 correct?
15:50:18 **A.** I am.
15:50:18 **Q.** And it looked at the presence of forced-air
15:50:21 warming; right? On plate 1 it was 1.13; on plate 2 it
15:50:26 was 1.07, and you even highlighted it in blue; plate 3
15:50:30 is 1.30; plate 4 is 1.55; and plate 5 and 6 are 1.0.
15:50:36 Is that correct?
15:50:37 **A.** Let me look. In the "absence of laminar
15:50:43 flow," you're looking at that, or the "presence of
15:50:44 forced air warming"?
15:50:45 **Q.** "Presence of forced air warming."
15:50:46 **A.** Yeah, that's correct.
15:50:47 **Q.** So with the presence of forced-air warming
15:50:49 there was an increase in bacterial load over the
15:50:52 surgical site.
15:50:53 MR. COREY GORDON: Object to the form of
15:50:54 the question.
15:50:54 **Q.** That's what those numbers mean; correct?
15:50:57 For four out of the six plates.
15:50:59 **A.** Oh, I see what you're saying. Yes.
15:51:00 **Q.** Okay.
15:51:01 **A.** For four out of the six, yeah.
15:51:03 **Q.** Okay. And you are aware that the -- only





15:51:47 one surgery dealt with total knee replacement.
15:51:50 **A.** I think that's right.
15:51:51 **Q.** Okay. Most of them were short surgeries;
15:51:54 correct?
15:51:54 **A.** Yes.
15:51:55 MR. COREY GORDON: Object to the form of
15:51:55 the question.
15:52:13 **Q.** Let's move on to page --
15:52:55 Go to page 34 [Exhibit 1].
15:53:20 (Discussion off the stenographic record.)
15:53:20 MR. ASSAAD: Let's take a break then.
15:53:23 (Recess taken from 3:53 to 4:02 p.m.)
16:02:55 BY MR. ASSAAD:
16:03:03 **Q.** Ready to continue, doctor?
16:03:04 **A.** Sure.
16:03:07 **Q.** Now let's look at page 34.
16:03:11 **A.** Okay.
16:03:12 **Q.** You go over three studies that talk about
16:03:14 the nasal colonization of Staph aureus?
16:03:27 **A.** Yeah.
16:03:28 **Q.** You agree with me that none of those studies
16:03:30 looked at the incidence of periprosthetic joint
16:03:34 infection; correct?
16:03:37 **A.** Let me see where I am here. (Witness
16:03:47 reviewing exhibit.) You're sure Kalmeijer? I just

16:03:51 can't remember exactly.
16:03:52 Do you have that paper, just remind me.
16:04:11 **Q.** I do have Kalmeijer, I only have one copy.
16:04:13 You don't have it with you?
16:04:14 **A.** No. I don't have anything.
16:04:16 **Q.** Okay. Well actually, let's look --
16:04:21 MR. COREY GORDON: He might in the box, if
16:04:23 not what's up there.
16:04:23 **A.** Yeah, I don't know.
16:04:25 **Q.** Let's look at Kalmeijer, which is the
16:04:26 surgical site in -- you can use my copy --
16:04:28 surgical-site infections in orthopedic surgeries.
16:04:31 Is that the paper you're referring to?
16:04:32 **A.** Yeah.
16:04:33 **Q.** Okay.
16:04:33 **A.** Is it -- If it's not joints, I just wanted
16:04:37 to make sure. I thought it included --
16:04:39 **Q.** Actually, if you look at the page that looks
16:04:41 at the number of patients, --
16:04:42 **A.** Yeah?
16:04:44 **Q.** -- you can see that in -- when mupirocin is
16:04:49 used --
16:04:50 **A.** Mupirocin, right.
16:04:51 **Q.** -- there were zero infections; correct?
16:04:54 **A.** Yeah.





16:04:54 **Q.** And then when the placebo is used there was
16:04:57 only one infection; correct?
16:04:58 **A.** Yes.
16:04:59 **Q.** That's not --
16:05:00 **A.** Deep infection.
16:05:01 **Q.** Yeah. And we're talking about deep
16:05:02 infections; correct?
16:05:03 **A.** Yes.
16:05:03 **Q.** That's not statistically significant; is it?
16:05:05 **A.** I don't think so.
16:05:06 **Q.** Okay. So would it be fair to say that if
16:05:10 you used --
16:05:12 Is it mupirocin?
16:05:13 **A.** Mupirocin, yeah.
16:05:14 **Q.** -- mupirocin, that there is no data that
16:05:16 indicates that it would statistically impact deep
16:05:21 joint infections?
16:05:21 **A.** In that study.
16:05:22 **Q.** In that study, okay.
16:05:24 And you consider this study authoritative;
16:05:26 correct?
16:05:26 **A.** Yes.
16:05:27 **Q.** Okay. What about the other studies? Do you
16:05:30 agree with me that none of them found that nasal --
16:05:39 nasal colonization of Staph -- of Staphylococcus had





16:05:44 any effect on periprosthetic joint infection?
16:05:48 **A.** Well I showed you the data from Chen, and in
16:05:53 the articles I even had the graph, I think, related to
16:05:55 that.
16:05:55 **Q.** I'm talking about page --
16:05:56 **A.** They were mixed --
16:05:57 **Q.** Okay.
16:05:58 **A.** -- deep and superficial, but they were
16:06:01 prosthetic joints.
16:06:02 **Q.** Those were the types of surgeries; correct?
16:06:05 **A.** Yeah. Is that what you want?
16:06:06 **Q.** No. But the difference is whether or not it
16:06:08 caused a superficial wound infection or a
16:06:10 periprosthetic joint infection. And there's no data
16:06:13 that having colonization of Staph in your nose has an
16:06:20 effect on periprosthetic joint infection; correct?
16:06:24 **A.** Yeah, I -- Again, Chen. Let's look at that,
16:06:27 because I thought --
16:06:29 Where do I have that in my notes? He has --
16:06:32 **Q.** What page are you referring to?
16:06:33 **A.** Well I'm trying to find it. Maybe it was
16:06:42 earlier. (Witness reviewing exhibit.) Sorry I'm
16:07:10 taking so long.
16:07:16 **Q.** Why don't you look at page 65?
16:07:19 **A.** 65?





16:07:20 **Q.** You talk about Chen, et al, Clinical
16:07:22 Orthopedic?
16:07:23 **A.** Yeah.
16:07:23 **Q.** Yeah. Page 65.
16:07:28 **A.** No, that's not right; is it?
16:07:32 **Q.** I'm sorry. Sixty-four.
16:07:34 **A.** Yeah, that's right. Okay. Thank you.
16:07:38 So, let's see. (Witness reviewing exhibit.)
16:07:46 What I remember that the study said is they mixed
16:07:55 superficial and deep in their review of the literature
16:08:00 because it wasn't always clear. So it might be a mix
16:08:04 of some of these.
16:08:06 **Q.** So sitting here today there is no evidence
16:08:09 or data that indicates having colonization of Staph in
16:08:14 your nose significantly increases the risk of
16:08:17 periprosthetic joint infection; correct?
16:08:18 MR. COREY GORDON: Object to the question,
16:08:19 mischaracterizes his testimony.
16:08:20 **A.** Well what I said is there's a mix of -- of
16:08:24 periprosthetic joint infections and the more
16:08:27 superficial ones in here, and I can't tell you, you
16:08:30 know, what proportion.
16:08:31 **Q.** Okay. So you have no opinion. You can't
16:08:33 make the statement today --
16:08:34 **A.** Oh, I make an opinion, yeah. I mean I would

16:08:37 -- You're going to surgery? Yeah, I'm going to tell
16:08:39 you before you take your hip get the mupirocin.
16:08:41 **Q.** I understand that.
16:08:42 **A.** That's my opinion.
16:08:43 **Q.** There's no data that --
16:08:45 I mean the only study that we have that
16:08:47 compared the two between a deep joint using --
16:08:57 **A.** Mupirocin.
16:08:58 **Q.** -- mupirocin and not is the Kalmeijer study;
16:09:02 correct?
16:09:03 MR. COREY GORDON: Object to the form of
16:09:05 the question, mischaracterizes his testimony.
16:09:06 **A.** Other -- What I just said, there's a mixture
16:09:09 here. I can't take out pure prosthetic joint
16:09:12 infections. Is that what you mean? Then I don't have
16:09:14 that. It's a mixture of periprosthetic joint
16:09:17 infections and the superficial ones, and she has five
16:09:21 studies here and they all show 50 percent reduction or
16:09:25 more.
16:09:25 **Q.** But they -- they might be a 50 percent
16:09:27 reduction in just superficial wound infections;
16:09:31 correct?
16:09:31 **A.** I don't think there were zero prosthetic
16:09:33 joint infections in these the way that article was.
16:09:35 **Q.** Can you --





16:09:36 I mean, if you wanted to do a study to look
16:09:38 at whether or not mupirocin reduces the incident of
16:09:45 periprosthetic joint infections, you have to look at
16:09:47 just periprosthetic joint infections; correct?
16:09:50 **A.** That's ideal, right.
16:09:51 **Q.** Okay. And one study we are aware of looked
16:09:54 at that, and that is the Kalmeijer study that you
16:09:58 consider authoritative; correct?
16:09:59 **A.** Yeah.
16:09:59 **Q.** Okay. And they saw no difference between
16:10:03 using mupirocin and not with respect to deep joint
16:10:07 infections; correct?
16:10:08 **A.** That's what they showed.
16:10:09 **Q.** And as of right now that is the only data
16:10:11 that we have available with respect to deep joint
16:10:15 infections. Solely on deep joint infections, not
16:10:18 combining everything together.
16:10:19 **A.** When you say it that way, "solely," yes.
16:10:21 **Q.** Okay. Because when you start looking at
16:10:23 superficial wound infections then you really have to
16:10:26 look at, you know, you really can't make a -- a -- a
16:10:34 reliable opinion with respect to periprosthetic joint
16:10:39 infections because for -- it could be possible that
16:10:42 you're looking at just a reduction in superficial
16:10:45 wound infections; correct?





16:10:47 MR. COREY GORDON: Object to the form of
16:10:48 the question.
16:10:48 **A.** Hypothetically, according to that, yeah. I
16:10:52 mean, it's --
16:10:53 **Q.** Okay. All right.
16:11:41 Now you agree -- Let's look at page 38.
16:11:51 **A.** Yeah.
16:11:54 **Q.** Okay. This is your discussion on your
16:11:57 opinions on laminar flow and rates of SSI; correct?
16:12:00 **A.** That's true.
16:12:02 **Q.** And Lidwell, the Lidwell studies were done
16:12:10 in the '80s; correct?
16:12:12 **A.** That's right.
16:12:13 **Q.** And then the Brandt study was done in --
16:12:17 recently; correct? 2008?
16:12:22 **A.** 2008 I have the publication.
16:12:24 **Q.** Okay. And Gastmeier's 2012; correct?
16:12:28 **A.** Gastmeier's two thou -- Yes.
16:12:30 **Q.** Okay. Now you would agree with me that
16:12:34 during the time that Lidwell was doing his -- his
16:12:37 studies, that the -- that the Bair Hugger wasn't used
16:12:42 in the operating room; correct?
16:12:45 **A.** Yeah, pretty sure it was not.
16:12:46 **Q.** Okay. But in the Brandt study and the
16:12:48 Gastmeier study you agree with me that the Bair Hugger





16:12:51 was used or could have been used in the operating
16:12:52 room; correct?
16:12:54 **A.** I would say "could have." I don't know. I
16:12:56 don't remember.
16:12:57 **Q.** Well based on your education, training and
16:13:00 experience, and your understanding of the use of the
16:13:01 Bair Hugger, can we agree that more likely than not
16:13:05 that the Bair Hugger was used --
16:13:06 **A.** I think it was --
16:13:07 MR. COREY GORDON: Object to the form of
16:13:09 the question, lack of foundation.
16:13:10 MR. ASSAAD: I didn't finish my question.
16:13:11 Can you please wait for me to finish my question?
16:13:13 MR. COREY GORDON: Sure.
16:13:14 **Q.** Based on your education, training and
16:13:16 experience, and your understanding of the Bair Hugger
16:13:19 and its use during operations, that more likely than
16:13:21 not that the Bair Hugger was used in the surgeries
16:13:25 that Brandt and Gastmeier reviewed?
16:13:28 MR. COREY GORDON: Object to the form of
16:13:30 the question, also lack of foundation.
16:13:33 **A.** So two thou -- The Bair Hugger's been in,
16:13:36 let's say 25, 30 years, so I would have thought so,
16:13:39 but again, I don't know.
16:13:40 **Q.** Okay. Are you aware that 3M admits that

every study that looked at whether or not the Bair Hugger increased particles or hydrogen bubbles over the -- Sorry. Strike that.

Are you aware that Bair -- 3M admits that every study indicates that whether you looked at hydrogen or particles, that both were increased when the Bair Hugger was turned on as compared to the Bair Hugger was turned off?

MR. COREY GORDON: Object to the form of the question, misstates the evidence.

**A.** So I'm not aware that 3M admitted that. No, I'm not aware of that.

**Q.** If that is the case, would that cause you any concern that the Bair Hugger increases particles over the surgical site?

**A.** What I know now it would cause me no concern because all the studies that get closer, looking at CFUs, can't show that.

**Q.** Well are you aware of the Stocks article that did a correlation between CFUs greater than 10 microns and --

**A.** Yes.

**Q.** -- and --

**A.** I'm sorry.

**Q.** -- and CFUs?





**A.** Yes.

**Q.** Do you agree with that study?

**A.** Yes.

**Q.** Okay. Page 46.

I just want to understand your CDC NNIS score.

**A.** Yeah.

**Q.** And I guess you look -- to determine the risk factor for a surgical site risk, one of the things you can look at is an NNIS score; correct?

**A.** Yes.

**Q.** Okay. And when you talk about the surgical-site infection risk, do you know whether or not the CDC is referring to a superficial wound infection or a periprosthetic joint infection?

**A.** I don't know for sure.

**Q.** Well that would be --

Since we're talking about, in this case, periprosthetic joint infections, that would be relevant; correct?

**A.** Yeah.

**Q.** Okay. Now if you look at the criteria --

Well what's your understanding of the length of time of a -- a -- and I might have asked you this -- a length of time for a total hip or total





knee?

**A.** I think they're around two hours.

**Q.** Okay. So you agree with me that most likely the last criteria you offer one point for if op time exceeds the seventieth percentile for that procedure, or greater than three hours for a joint --

(Interruption by the reporter.)

**Q.** -- if op time exceeds the 75th percentile for that procedure, or greater than three hours for the joint replacement, that we could probably eliminate greater than three hours as one of the criteria that would be -- apply to total hip and total knee.

MR. COREY GORDON: Object to the form of the question, --

**A.** These --

MR. COREY GORDON: -- lack of foundation.

**A.** These are not my criteria, these are, you know, CDC's, and I don't think today there would be that many patients who would have more than three hours.

**Q.** Okay. And we could agree that for total hip and total knee it's not a contaminated or dirty surgery; correct?

**A.** Yes. It's a clean surgery.





**Q.** Okay. And the ASA score is based on the patient; correct?

**A.** It is.

**Q.** Okay. Now where it says, "if op time exceeds the 75th percentile for that procedure," is there somewhere I could look at to see what the -- the time for each type of procedure is?

**A.** I think there is, but I -- I don't know the CDC reference for that, though.

**Q.** Okay. Looking at the bottom, the odds ratio of the variables.

**A.** Yeah.

**Q.** Why is it if you have private insurance you're less likely to get a surgical-site infection?

**A.** My guess is that it's a surrogate for healthier people who are less likely to have some of the other comorbidities. I don't know the answer, but that's my thought.

**Q.** Go to page 49.

**A.** Okay.

**Q.** You write: "Of interest, there were no prosthetic joint infections...among diabetics who were not obese..."

Did I read that correctly?

**A.** You did.

16:20:16 **Q.** So would you agree with me that the mere
16:20:18 fact that you have diabetes, that it does not increase
16:20:24 the risk of periprosthetic joint infection?
16:20:27 **A.** No, I wouldn't. This is this study, and
16:20:29 that's what I would cite to say in that study that's
16:20:31 what they found.
16:20:32 **Q.** Okay. Well what's your opinion, sir?
16:20:35 **A.** I think diabetes is a risk factor.
16:20:36 **Q.** Okay. So you disagree with the --
16:20:36 **A.** I do.
16:20:37 **Q.** -- the results of the study.
16:20:38 **A.** I do.
16:20:40 **Q.** Okay. But you cited this study in your
16:20:42 report.
16:20:42 **A.** Sure. I told you I'm trying to show you
16:20:45 everything I have.
16:21:32 **Q.** And you would consider obese a BMI greater
16:21:35 than 30; correct?
16:21:35 **A.** Yes.
16:21:58 **Q.** And you'd agree with me that there is a big
16:22:00 difference with respect to risk factors of
16:22:03 surgical-site infections between obese and morbidly
16:22:06 obese.
16:22:07 **A.** Yeah, I think it's probably worse with
16:22:09 morbid obesity, yeah.





16:22:10 **Q.** And I believe you cited an article you
16:22:12 looked at where they looked at the BMI greater than 30
16:22:15 and the BMI greater than 40. Is that -- Am I
16:22:18 recalling that correctly?
16:22:19 **A.** You may. I can't think it -- I don't know
16:22:21 what that is right now, but it might be so.
16:23:27 **Q.** So I understand that you read many articles
16:23:39 and did an extensive literature search with respect to
16:23:42 formulating your opinions in this case; correct?
16:23:48 **A.** Yes.
16:23:49 **Q.** Okay. So when you come to your ultimate
16:23:51 opinions, what methodology did you use in doing your
16:23:55 review to determine your opinions?
16:24:05 **A.** What I think I've done is actually take a
16:24:08 look at the hierarchy of all the studies that fell
16:24:13 into any one group. So I looked separately at
16:24:16 clinical trials, I looked at meta-analysis,
16:24:20 case-control studies, cohorts, national trends, and
16:24:25 then the data on CFUs as a biological plausibility. I
16:24:31 have -- There are 15 studies from there. I looked at
16:24:37 the particle studies, which I think are really distant
16:24:41 surrogate markers of infection. And then together, I
16:24:46 would say, as -- as a complete package, I can't find
16:24:53 any, you know, convincing link between the Bair Hugger
16:24:59 and harm.





16:25:01 We can talk about the McGovern study as the
16:25:06 one sort of study that stands out until recently.
16:25:09 They gave an initial signal, but the more I looked at
16:25:14 that study, the more problems I had with it.
16:25:30 **Q.** With respect to your methodology to de --
16:25:33 Strike that.
16:25:33 We've talked about some studies today in
16:25:37 which they offered data or opinions that contradict
16:25:41 your opinions; correct?
16:25:43 **A.** There were some.
16:25:44 **Q.** Okay. What was your methodology to de -- in
16:25:47 determining which studies you would use to support
16:25:50 your opinions and which studies that you would
16:25:52 disregard?
16:25:55 **A.** I don't know that I would sort of just
16:25:57 blatantly disregard anything. I looked at the
16:26:00 collective sort of sense within each category, if I
16:26:05 could.
16:26:05 **Q.** Well, for example, you think that nasal
16:26:12 colonization of Staph will have an effect on
16:26:15 periprosthetic joint infection, but you disregard the
16:26:18 only study that looks at it that says there is no
16:26:22 statistically significant difference.
16:26:23 MR. COREY GORDON: Object to the form of
16:26:24 the question, mischaracterizes his testimony.





16:26:25 **A.** I think the -- the bulk of data, so many
16:26:31 different studies, including orthopedic studies where
16:26:33 I gave you from Chen, there is no way that I would
16:26:36 want the orthopedic patient not to have nasal
16:26:40 mupirocin preoperatively, and that's pretty much the
16:26:44 standard around the country.
16:26:46 **Q.** Well that's not the standard where Darouiche
16:26:47 did his study; correct?
16:26:49 MR. COREY GORDON: Object to the form of
16:26:50 the question, lack of foundation.
16:26:51 **A.** Yeah, I -- I -- he -- that study, no. In
16:26:55 terms of that study, he didn't do that, but --
16:26:57 **Q.** Okay. So --
16:26:58 **A.** -- that wasn't prosthetic joint infections.
16:27:01 Are you talking about the first study?
16:27:02 **Q.** Yes.
16:27:03 **A.** Of the -- Using the antiseptic?
16:27:06 **Q.** Yeah.
16:27:06 **A.** Yeah, that's -- that's obviously different
16:27:09 than prosthetic joints.
16:27:11 **Q.** So you would use it for prosthetic joints
16:27:12 but not for other surgeries?
16:27:15 **A.** Yeah, there -- I -- I think the standards
16:27:15 are today, any implant; so orthopedic implant, cardiac
16:27:21 implant, and neurosurgery implant, all those people

should be getting mupirocin and chlorhe -- and chlorhexidine baths.

**Q.** And the mupirocin is for the nose; correct?

**A.** It is.

**Q.** Okay. So that would indicate to me that you are trying to kill the bacteria in the nose so it doesn't become aerosolized; correct?

MR. COREY GORDON: Object to the form of the question.

**A.** No, that's not the... I'm trying to kill the bacteria in the nose, and if you kill the bacteria in the nose you actually show a markedly reduced bacterial burden in the rest of the body.

**Q.** How does that occur?

**A.** You know, the joke that I use is think about all the people that touch their nose when they -- you know, during the day, and 30 to 50 percent of people who have Staph aureus in the nose have this on the strai -- on their hands, and when you do fingerprints, 97 percent are the exact same strain. So I don't know for sure, but I think that we all have a lot of contact with our nose and mouth.

**Q.** And when do you give the mupirocin to the patient?

**A.** Ideally you would have them come into the





pre-op center and -- where they get evaluated in general for anesthesia five days before the surgery, and then twice a day for five days.

**Q.** So I'm just trying to understand, like, when you look at a -- a peer-reviewed article, what methodology do you have to determine whether or not the article is something that you're going to rely upon and agree with as compared to something that you may not agree with?

**A.** Well I could go on for a long time, but I think what I would do is look at the methods section in a very critical way. For example: Did they have a clear hypothesis? Did they have a clear endpoint? If they're counting infections, what was the method of case finding? Was there any validity to the case finding technique? You know what I mean by that? When I say -- I'm going to go back. If they say they found it, was it really a case, or was it a mistake? Was it -- What kind of study was it really; a prospective, a clinical trial, was it observational trial? If it was observational, were the two things that we're interested in looked at concurrently? I'd want to know a little bit about how they, you know, did some power studies, what Alpha was in the study, and the length of follow-up, of course, would be all





important things. I'd want to look at what statistics that they used and how they were going to evaluate success or not. And I would hope that they would have not only efficacy, but a safety profile to go along by which you could make a, if you will, risk/benefit compared to an alternative.

I could go on for awhile, but I think you got the idea.

**Q.** I think I get the idea.

MR. ASSAAD: So let's mark this as the next exhibit.

(Wenzel Exhibit 12 marked for identification.)

(Discussion off the stenographic record.)

BY MR. ASSAAD:

**Q.** Do you --

Have you seen this article before?

**A.** I don't know. I'm not sure I have, but.

**Q.** I represent to you that it came out of the box of documents that you provided to us today.

**A.** Yeah. You know, when you read a lot, I'm not positive. I want to be able to tell you accurately.

**Q.** And if you look at a couple pages later, I think the next page, it's actually underlined in





certain areas.

**A.** Okay. (Witness reviewing exhibit.) Oh, in the "DISCUSSION." What do you want me to tell you?

**Q.** I mean, is that your underlining?

**A.** Oh yeah, it is.

**Q.** Can I look at it real quick, please?

**A.** Yeah, sure. (Handing.)

**Q.** You highlighted, in the --

And what Exhibit 12 is is the article titled *Forced-Air Warming Does Not Worsen Air Quality in Laminar Flow Operating Rooms,* authored by Dr. Sessler, Dr. Olmsted and Kuelpmann. Is that correct?

**A.** I think they're the authors, yeah. Yeah.

**Q.** Why wasn't this article, which is clearly something you reviewed, in -- somewhere in your report?

**A.** I don't know. Don't remember.

**Q.** Were you told by anyone not to include this article in your report?

**A.** First of all, no one's told me anything, and I wouldn't listen anyway.

**Q.** Okay. You underline, "Our results are consistent with computational fluid dynamic models that show that properly designed air handling systems combined with natural protective aspects of convective

16:33:46 currents up from the patient, are effective in
16:33:49 reducing particle concentrations" near surgical --
16:33:51 "near the surgical site."
16:33:54 **A.** Yeah. That's what he said.
16:33:56 **Q.** Well my question is why did you underline
16:33:58 that section?
16:34:02 **A.** You know, a lot of times I underline things
16:34:04 because, one, I don't understand and I want to read it
16:34:07 a second time, or I wanted to ask a question from
16:34:09 counsel. And as I told you earlier, I'm one of these
16:34:13 guys that often underlines, you know, a big chunk of
16:34:16 the re -- if you gave me a novel, unfortunately, I'd
16:34:20 ask you if you wanted it back because I underline that
16:34:23 stuff.
16:34:24 **Q.** So sitting here today you don't know why you
16:34:26 underlined it?
16:34:27 **A.** I don't remember.
16:34:28 **Q.** Okay. Now do you recall --
16:34:31 You said you've read the Sessler
16:34:33 depositions; correct?
16:34:34 **A.** I think so. I don't remember a lot of -- I
16:34:36 thought I had.
16:34:37 **Q.** Do you recall the discussion I had with Dr.
16:34:41 Sessler during his deposition regarding his tests?
16:34:44 **A.** No, but go ahead. Remind me.





16:34:48 **Q.** You haven't seen the raw data for -- for --
16:34:50 You haven't seen the raw data for the -- for
16:34:53 this study; correct?
16:34:54 **A.** Correct.
16:34:54 **Q.** Okay. Now just so I understand your
16:35:10 opinion, if a device significantly increases particles
16:35:19 over the surgical site is it your opinion that the --
16:35:37 there is going to be no effect on surgical-site
16:35:40 infections?
16:35:40 MR. COREY GORDON: Object to the form of
16:35:43 the question, also incomplete hypothetical.
16:35:44 **A.** You know, I hate to say "always" or "never,"
16:35:47 I've told you that today. So I'd hate to say "never,
16:35:51 ever." But in general for me to think that particles
16:35:56 are really important would be if that was linked
16:35:59 directly in some way to surgical-site infections and
16:36:03 not just be a surrogate marker.
16:36:06 **Q.** You agree with me that Stocks linked
16:36:08 particles to bacteria for particles greater than 10
16:36:12 microns; correct?
16:36:12 **A.** He did. I agreed.
16:36:13 **Q.** And you agree that Darouiche linked CFUs to
16:36:20 -- the -- the amount of CFUs to periprosthetic joint
16:36:25 infections; correct?
16:36:25 MR. COREY GORDON: Object to the form of





16:36:26 the question.
16:36:26 **A.** Yeah. That was his link, yes.
16:36:30 **Q.** And you agree with that?
16:36:31 **A.** Yeah.
16:36:32 (Interruption by the reporter.)
16:36:32 **A.** His link, yeah.
16:36:32 **Q.** Okay. So if you're looking at just 10
16:36:35 micron particles, would you agree with me that an
16:36:37 increase in 10 micron particles over the surgical site
16:36:40 would increase the risk of periprosthetic joint
16:36:42 infection?
16:36:43 MR. COREY GORDON: Object to the form of
16:36:44 the question, incomplete hypothetical.
16:36:46 **A.** That's the question that we're trying to get
16:36:48 at, and I don't think we have conclusive information
16:36:52 that particles equal infections.
16:36:54 **Q.** Are you looking for a hundred percent
16:36:55 certainty?
16:36:56 **A.** I never look for a hundred percent, sir.
16:36:59 **Q.** Well do you remember back in, maybe it was
16:37:04 high school, we had to learn logic? Remember that?
16:37:08 **A.** Yeah. I took a college, not high school
16:37:11 course, in logic.
16:37:12 **Q.** Okay. You know, if you -- A -- you know, if
16:37:15 A equals B and B equals C, then A could equal C?





16:37:19 **A.** I know what you're getting at.
16:37:20 **Q.** You remember that?
16:37:21 **A.** Yeah.
16:37:21 **Q.** Okay. So --
16:37:21 MR. COREY GORDON: Socrates was a man.
16:37:25 **Q.** So if -- if Stocks linked particles over 10
16:37:31 microns to bacterial load, and Darouiche linked
16:37:41 bacterial load to periprosthetic joint infections, and
16:37:46 I understand you have an issue with where is that
16:37:51 bacteria coming from, but based on those two studies,
16:37:53 and logic, do you not agree that if 10 micron
16:37:57 particles increase over the surgical site there is
16:38:00 going to be an increase in periprosthetic joint
16:38:02 infections?
16:38:02 MR. COREY GORDON: Object to the form of
16:38:03 the question, also lack of foundation, incomplete
16:38:06 hypothetical.
16:38:08 **A.** Well I like the logic part, but if you're
16:38:12 talking about Darouiche's study based on four
16:38:16 infections, even he says we need to go back and get a
16:38:21 much bigger study to see if this is real. That's
16:38:24 my -- my recollection of what he did in the
16:38:27 discussion.
16:38:28 No one's going to take that kind of study
16:38:31 and make a blanket statement about all surgeries.

16:38:34 **Q.** But you, sitting here, cannot say that my
16:38:38 statement is not true; correct?
16:38:42 **A.** I --
16:38:42 MR. COREY GORDON: Object to the form of
16:38:43 the question.
16:38:44 **A.** I don't think it's true. I think it's -- we
16:38:46 need a lot more information for your statement --
16:38:46 **Q.** Okay.
16:38:49 **A.** -- to be right, unless you're making it
16:38:52 totally hypothetical.
16:38:53 **Q.** I didn't ask you if it was true.
16:38:54 You can't offer the opinion that that --
16:38:57 that that progression between Stocks and Darouiche and
16:39:05 particles over 10 microns can be correlated to
16:39:17 periprosthetic joint infections is not true.
16:39:19 MR. COREY GORDON: Object to the form of
16:39:20 the question, --
16:39:20 **Q.** You just want more data.
16:39:22 MR. COREY GORDON: -- in --
16:39:23 Object to the form of the question,
16:39:24 incomplete hypothetical.
16:39:26 **A.** Well I want more data, and also, you know,
16:39:31 I'd say if you -- Well, let me pause for a second.
16:39:37 I'm trying to -- I'm getting a little tired, I think.
16:39:40 **Q.** Let me withdraw the -- Let me make it a





16:39:41 little bit easier, okay, because I know it's a lot of
16:39:44 thinking.
16:39:44 For example, if Darouiche came out and came
16:39:46 up with -- did the same exact study and showed no
16:39:49 correlation between CFU load over the surgical site
16:39:52 and periprosthetic joint infections, then there would
16:39:55 be no need for a further study because that study
16:39:58 indicated that it's irrelevant; correct?
16:40:01 **A.** If a --
16:40:01 MR. COREY GORDON: Object to the form of
16:40:02 the question, incomplete hypothetical.
16:40:04 **A.** If a new study came out, much bigger and
16:40:06 showed there's nothing going on, yeah, I think that
16:40:09 would be the end, or -- or certainly close.
16:40:13 **Q.** My point is, further study is needed;
16:40:17 correct?
16:40:18 **A.** For sure.
16:40:19 **Q.** Okay. And the reason why you think further
16:40:21 study is needed, because you can't exclude the fact --
16:40:23 the scenario that if you increase 10 micron particles
16:40:27 over the surgical site it would have no effect on
16:40:32 periprosthetic joint infections.
16:40:33 **A.** I've seen --
16:40:33 MR. COREY GORDON: Object to the form of
16:40:36 the question, incomplete hypothetical.





16:40:37 **A.** -- just no data that I can say to answer
16:40:38 that no, so that's right.
16:40:40 **Q.** But you can't exclude it either; can you?
16:40:42 **A.** I can never exclude things that aren't
16:40:44 there.
16:40:45 **Q.** Okay. Especially after the Stocks and
16:40:46 Darouiche study; correct?
16:40:49 **A.** Yeah.
16:40:50 **Q.** Okay.
16:40:50 **A.** I mean that's...
16:40:51 **Q.** Let's talk about heater-cooler.
16:40:53 **A.** About what?
16:40:53 **Q.** The heater-cooler.
16:40:54 **A.** Okay. Sure.
16:41:02 **Q.** And I believe that's on page 75.
16:41:15 **A.** Yeah.
16:41:22 **Q.** Now you understand that the heater-cooler
16:41:24 device is not near the surgical table.
16:41:28 **A.** The device itself is away from the table,
16:41:30 yeah.
16:41:31 **Q.** It's actually probably in the corner of the
16:41:33 room.
16:41:33 **A.** Often far away, yeah.
16:41:34 **Q.** Okay. And it is -- it has tubes that carry
16:41:40 water to either heat or cool down the patient;





16:41:42 correct?
16:41:43 **A.** Yes.
16:41:43 **Q.** Okay. And the water is --
16:41:45 It's a closed system; correct?
16:41:47 **A.** It's not so closed as -- as what I've heard
16:41:50 from our perfusionist.
16:41:53 Oh, that part, the tubing is.
16:41:54 **Q.** Yeah.
16:41:55 **A.** Yeah, not the tank of water.
16:41:57 **Q.** Which is -- the tank --
16:41:58 **A.** I'm sorry.
16:41:58 **Q.** -- the tank's in the corner of the operating
16:42:00 room; correct?
16:42:01 **A.** The tank is, yeah.
16:42:02 **Q.** Okay. But the --
16:42:02 **A.** And they have --
16:42:02 **Q.** -- tube is closed; correct?
16:42:05 **A.** -- tubes that -- tubes are closed.
16:42:07 **Q.** Okay. And it might not -- there might be
16:42:08 some leaks or some vapor inside the -- the
16:42:11 heater-cooler unit; correct?
16:42:13 MR. COREY GORDON: Object to the form of
16:42:14 the question.
16:42:14 **A.** You're talking about above the tank of
16:42:16 water?

16:42:16 **Q.** Or -- Or inside the heater-cooler unit where
16:42:18 the tank is, it might -- there might not be fully
16:42:22 closed or there might be some leakage or vapor.
16:42:24 MR. COREY GORDON: Object to the form of
16:42:25 the question, also lack of foundation.
16:42:26 **Q.** Let me ask you this. Why do you -- Why do
16:42:28 you not think it's a closed system at the
16:42:32 heater-cooler device?
16:42:32 **A.** Well, I mean, you just open up the thing a
16:42:34 little bit, I had the perfusionist show me this when
16:42:38 they started to have infections about a year and a
16:42:40 half ago, and you can just see this big tank of water.
16:42:43 **Q.** Okay. And what do you see?
16:42:45 **A.** And there's a fan right behind it, yeah.
16:42:47 **Q.** Okay. And -- And you're saying the fan is
16:42:50 blowing the water?
16:42:51 **A.** It's blowing above the water.
16:42:53 **Q.** Okay. And what does that cause?
16:42:54 **A.** Aerosol.
16:42:55 **Q.** Aerosol that could be contaminated?
16:42:58 **A.** This study they showed that the air
16:43:01 contained Mycobacterium chimaera.
16:43:01 **Q.** Okay. And it actually reached the patient;
16:43:09 correct?
16:43:09 (Interruption by the reporter.)





16:43:09 **Q.** And it actually reached the patient;
16:43:12 correct?
16:43:12 **A.** It did.
16:43:12 **Q.** And so it was an airborne contamination that
16:43:15 caused the infection to the patient; correct?
16:43:17 **A.** Yes.
16:43:25 MR. COREY GORDON: It's actually
16:43:34 "Mycobacterium chimaera."
16:43:37 THE REPORTER: Thank you.
16:44:23 **Q.** You do not dispute the fact that the Bair
16:44:27 Hugger harbors bacteria, --
16:44:27 MR. COREY GORDON: Object --
16:44:29 **Q.** -- the device itself.
16:44:31 MR. COREY GORDON: Object to the form of
16:44:32 the question, incomplete hypothetical, lack -- lack
16:44:33 of foundation.
16:44:34 **A.** So there've been some cultures of the tubing
16:44:38 that have shown organisms, and some have been swabbed,
16:44:44 some have been rinsed, I think, and I think I showed
16:44:48 these in my report, everything that -- that I knew
16:44:52 about that.
16:44:55 **Q.** So you don't dispute that the Bair Hugger is
16:44:58 contaminated internally.
16:44:59 MR. COREY GORDON: Object to the form of
16:45:01 the question.





16:45:01 **A.** It -- In some studies they found bacteria.
16:45:04 It's not sterile.
16:45:05 **Q.** Okay. And it can't be cleaned; correct?
16:45:08 MR. COREY GORDON: Object to the form of
16:45:09 the question, lack of foundation.
16:45:10 **A.** I've read that, but I don't know, I mean.
16:45:13 **Q.** Well you've seen the device; correct?
16:45:14 **A.** Yeah. I have.
16:45:16 **Q.** Are you aware of anyone that's ever cleaned
16:45:18 the inside of the hose of a Bair Hugger?
16:45:21 MR. COREY GORDON: Inside of the hose?
16:45:22 MR. ASSAAD: Inside the hose.
16:45:23 MR. COREY GORDON: Object to the form of
16:45:24 the question, lack of foundation.
16:45:25 **A.** Oh, inside the hose. You're not talking
16:45:27 about the -- you know, the blower itself?
16:45:30 **Q.** The blow --
16:45:31 or the blower or anything.
16:45:32 **A.** Well Bernard, in his study, said he did it
16:45:35 because he thought it was important.
16:45:38 **Q.** Okay. But have you looked at the operating
16:45:40 room manual?
16:45:42 **A.** Have I looked --
16:45:43 **Q.** Yeah.
16:45:43 **A.** Oh, no. I haven't looked at that, no.





16:45:45 **Q.** Why not?
16:45:46 **A.** I think I had enough to do I guess trying to
16:45:50 get this report together, and...
16:45:53 **Q.** You spent over 300 hours, why not spend
16:45:56 another hour on the report -- or looking at the
16:45:57 manual?
16:45:58 MR. COREY GORDON: Object to the form of
16:46:00 the question.
16:46:00 **A.** I mean -- I mean, I guess I'm more
16:46:01 interested in the infections and the outcomes than,
16:46:05 you know, how it worked, and so I didn't look at it.
16:46:10 **Q.** Do you know the difference between the Model
16:46:12 505 and the Model 750?
16:46:16 **A.** I understand there was a filter that was
16:46:17 different.
16:46:17 Do I have the right -- Is that correct? I'm
16:46:19 trying to think if I have the right statement.
16:46:22 **Q.** Well, I'm not going to answer questions.
16:46:25 I'm asking you questions.
16:46:26 **A.** Yeah. No, that's --
16:46:27 **Q.** Do you know the difference in the airflow?
16:46:28 **A.** No.
16:46:33 **Q.** Do you know the difference in the amount of
16:46:34 heat it produces?
16:46:35 **A.** No.

16:47:00 **Q.** Do you know what a thermal plume is?
16:47:02 **A.** What is what?
16:47:02 **Q.** A thermal plume.
16:47:04 **A.** No. I would assume it's --
16:47:05 No, I don't know what it is, but.
16:47:19 (Discussion off the stenographic record.)
16:47:26 **Q.** Have you reviewed studies that indicate that when the Bair Hugger is turned on that it actually increases the temperature around the surgical table?
16:47:34 **A.** Yes, I think it does.
16:47:36 **Q.** So you agree with that?
16:47:37 **A.** At least some studies have, yeah.
16:47:39 **Q.** You don't dispute that; correct?
16:47:40 **A.** No.
16:47:41 **Q.** And it makes sense; right?
16:47:42 **A.** Makes sense, too.
16:47:44 **Q.** Yeah.
16:48:14 (Discussion off the stenographic record.)
16:48:14 **Q.** And you would agree that that -- that the Bair Hugger's blowing heat down underneath -- above the -- like over the patient and then it goes down towards underneath the operating room table; correct?
16:48:27 MR. COREY GORDON: Object to the form of the question, lack of foundation.
16:48:29 **A.** I think it goes down, but I'm -- I told you





16:48:32 earlier I wasn't an expert in aerodynamics and --
16:48:32 **Q.** Okay.
16:48:35 **A.** -- didn't look at all those, you know, computational studies.
16:48:37 **Q.** You've written many research papers; correct?
16:49:07 **A.** Yes.
16:49:10 **Q.** Peer-reviewed papers; correct?
16:49:11 **A.** Yes.
16:49:12 **Q.** And do you agree with me that when you do a study, the paper should include enough methodology in the methods section so the study could be repeatable; correct?
16:49:12 **A.** Yes.
16:49:23 **Q.** Okay. And that's how you determine whether or not the study is reliable; correct?
16:49:24 **A.** Well it helps, yeah.
16:49:27 **Q.** Okay. Because with -- you know, repeatability is pretty much synonymous with reliability; correct?
16:49:29 **A.** Yeah, I would think that's reasonable.
16:49:31 **Q.** Now with respect to maintaining normothermia, you're not advocating for one device over another; are you?
16:49:33 **A.** In terms of general for the patients to





16:50:15 remain?
16:50:16 **Q.** Yes.
16:50:17 **A.** No, I'm not. As long as the patients are warm, I think they'll probably do okay.
16:50:21 **Q.** So just so I understand, you're not here advocating that the Bair Hugger device is better than the Mistral device; correct?
16:50:24 **A.** Actually is that the one that's just been tested by Kurz; is that the Cleveland Clinic?
16:50:27 **Q.** Yes.
16:50:29 **A.** Yeah. Actually they look like they were the same, but there's actually, as you know, a lower rate with the Bair Hugger than with the HEPA filter forced-air warming, it's .44 versus .74 I think.
16:50:32 **Q.** Okay. Any criticism of that study?
16:50:34 **A.** It was a remarkably robust study. You're talking about 5,000 patients and they did something, you know, and they have the part of their prospective cohort, and they did multivariate analysis and they looked at comorbidities. So a huge study. And with the Bair Hugger a rate of .44, which I think is percent, that's as good as anywhere in the world.
16:50:38 **Q.** Well that's similar to what McGovern did, isn't it? He just -- They stopped using one product, then used another and they did a comparison; correct?





16:50:39 **A.** Yeah. He left out all the issues related to confounding and bias, and --
16:50:42 **Q.** In the Cleveland Clinic study; correct?
16:50:45 **A.** No, no. The Cleveland Clinic has all the -- they have a multivariate analysis before they put out their report.
16:50:49 **Q.** Did they look at their infection rates overall during the time periods of 2013 and 2015?
16:50:53 **A.** Did they do what?
16:50:54 **Q.** Did they look at the infection rates overall, over all surgeries?
16:50:57 **A.** Umm --
16:51:00 **Q.** Do you know that, whether or not, whether they did that?
16:51:02 **A.** This is -- I think it was all prosthetic joint is what I recall, Kurz.
16:51:06 **Q.** You understand that Cleveland Clinic's a teaching hospital; correct?
16:51:12 **A.** It is.
16:51:14 **Q.** And they have a lot of residents; correct?
16:51:18 **A.** Correct.
16:51:19 **Q.** And infection rates may depend on the attending and the residents; correct?
16:51:23 **A.** There's some data for that, sure.
16:51:24 **Q.** There's a lot of data for that; correct?

16:52:08 **A.** Yeah.
16:52:09 **Q.** And they didn't look at, you know, using the Mistral and the Bair Hugger at the same time, they looked at at different time periods; correct?
16:52:15 **A.** That's true.
16:52:16 **Q.** So there could be different physicians doing the surgeries; correct?
16:52:18 **A.** Yeah.
16:52:19 **Q.** Different residents?
16:52:20 **A.** Yeah.
16:52:20 **Q.** Okay. There could be different skin preps during those times in those two years?
16:52:28 **A.** Yeah, I don't know the answer to that.
16:52:30 **Q.** Exactly. We don't know the answer to that, do we? Okay.
16:52:34 **A.** I don't. Somebody might.
16:52:35 **Q.** We agree that --
16:52:37 Could you agree with me that the difference was not statistically significant?
16:52:38
16:52:40 **A.** Correct.
16:52:41 **Q.** Okay. You're not offering those criticisms for -- for that study; are you?
16:52:44
16:52:45 **A.** No. I would tell you right away exactly the data.
16:52:47
16:52:48 **Q.** But you're not offering, so I had to





16:52:52 actually pull them out of you; correct?
16:52:53 **A.** Well I gave --
16:52:53 MR. COREY GORDON: Object to the form of the question.
16:52:55
16:52:55 **Q.** Right?
16:52:55 **A.** I was trying -- I mean I was trying to get your answer to, you know, is there any difference between the two devices.
16:52:56
16:52:58
16:53:01 **Q.** And we haven't seen -- we haven't looked at the --
16:53:03
16:53:04 This is just the poster presentation; correct?
16:53:05
16:53:07 **A.** Yeah.
16:53:08 **Q.** Have you seen the manuscript?
16:53:10 **A.** I think I've seen the manuscript, I'm trying to remember, or at least a draft of something. It might be just an enlarged poster.
16:53:12
16:53:15
16:53:18 **Q.** Well which was it? Did you see --
16:53:19 I want to talk either about the manuscript or the poster. Which one you want to talk about?
16:53:21
16:53:23 **A.** Let's talk about the poster is fine.
16:53:24 **Q.** Have you looked at the manuscript?
16:53:26 **A.** I think I saw more data than just the poster, yeah.
16:53:29
16:53:29 **Q.** Okay. What data else did you see?





16:53:31 **A.** What?
16:53:32 **Q.** What other data did you see?
16:53:34 **A.** Besides what?
16:53:35 **Q.** I mean, what data did you see about that study with respect to the -- the Cleveland Clinic study besides the poster?
16:53:37
16:53:43
16:53:45 **A.** Well I'm not sure I saw anything, but I thought I saw an expanded poster, I guess. I don't -- I don't know.
16:53:47
16:53:51
16:53:51 **Q.** Is it in your box of documents?
16:53:55 **A.** I hope so.
16:54:00 MS. ZIMMERMAN: I didn't see it. I could be wrong.
16:54:01
16:54:02 THE WITNESS: Yeah, I'm sorry.
16:54:03 MS. ZIMMERMAN: No. No. That's all right.
16:54:05 **Q.** By the way, are there -- are there documents that you did not print up that you looked on -- that you have on your computer?
16:54:07
16:54:09
16:54:11 **A.** No.
16:54:12 **Q.** So every document you reviewed you printed up and highlighted or have done something with it.
16:54:15
16:54:16 **A.** Yeah. I don't like to read stuff on the computer.
16:54:19
16:54:19 **Q.** Okay.
16:54:19 **A.** I'm old.





16:54:26 MR. COREY GORDON: Gabe, I'll just represent, he hasn't -- the only thing he's seen is what was attached to Mont's report. There is no -- however you want to characterize it, there's no other data that he or I or anyone connected with the plaintiffs -- or with the -- with this litigation has seen.
16:54:27
16:54:30
16:54:32
16:54:34
16:54:38
16:54:40
16:54:45 **Q.** So you're sitting here advocating for the Bair Hugger as a better device than the Mistral?
16:54:48
16:54:51 **A.** I'm not advocating for them. I'm saying that after review of the literature I've come to the conclusion that the Bair Hugger is not linked in any way to harm.
16:54:54
16:54:56
16:54:59
16:55:03 **Q.** Okay. And what about -- I mean -- Strike that.
16:55:07
16:55:08 But with respect to patient warming, as long as the patient is kept warm, you don't care what method is used; correct?
16:55:13
16:55:17
16:55:18 **A.** Right now I think there are no data to show that if the patients are warmed by anything else, particularly after the Kurz study, you have that warmer as an additional one. It looked the same.
16:55:21
16:55:24
16:55:27
16:55:31 **Q.** Which warmer?
16:55:31 **A.** The HEPA -- the forced-air warmer. So that's probably the best data I could point to.
16:55:37

16:55:39 **Q.** Are you aware of the CDC indicating that there should be nothing in the OR that blows air?
MR. COREY GORDON: Object to the form of the question, mis --
**A.** I've read --
MR. COREY GORDON: -- misstates the -- mischaracterizes the evidence.
**A.** I've read the document where they said that, and actually looked at their in-progress, I guess, guideline from December 2016, and they really talk about the air-water interface when they're giving that statement.
I should also say that, because I wanted to be sure, I called the director of the CDC's quality healthcare, I forget what the -- that whole division that oversees HICPAC, and she told me they -- you know, this wasn't pertaining to forced-air warming, it was worry -- their big concern was when, you know, the heater-cooler unit was identified as a really source of serious infection.
**Q.** What was her name?
**A.** It is Denise A. Cardo.
**Q.** How do you spell that, for the court reporter?
**A.** C-A-R-D-O.





16:56:52 **Q.** And when did you contact her?
**A.** In the last couple weeks.
**Q.** Did you contact her at the request of counsel?
**A.** No. They didn't know I did that.
**Q.** Okay. Did you bill it on your -- in your invoice?
**A.** No, I didn't.
**Q.** Okay. And do you have a record of this conversation?
**A.** No, I don't.
**Q.** How did you get her phone number?
**A.** Called CDC, got ahold of her former assistant, because the numbers don't carry over sometime when there's some movement, and she said, well you need to talk to this person's assistant. Gave me the assistant, I left a message and asked her if there was a good time when I could call.
MR. ASSAAD: Take a break?
THE REPORTER: Please. Thank you.
(Recess taken from 4:57 to 5:05 p.m.)
BY MR. ASSAAD:
**Q.** Doctor, turning to page 62?
**A.** Okay.
**Q.** 62 begins your critique of the McGovern





study; correct?
**A.** The clinical arm.
**Q.** Yes. Of the McGovern study; correct?
**A.** Yeah. Yes.
**Q.** And you go on for about, from page 62 to page 68; correct?
**A.** Let me see. Yes.
**Q.** You did not do a critical critique of any other study that -- that you looked at, such as you did with the McGovern study; correct?
**A.** That's probably true.
**Q.** Okay. You didn't do any critiques of --
(Cell phone interruption.)
MR. COREY GORDON: Sorry.
**Q.** -- the Sessler study we just looked at; correct?
**A.** True.
**Q.** You didn't do any critical critiques of the Huang study; correct?
**A.** Yeah.
**Q.** Okay. Or the Moretti study; correct?
**A.** Yes.
**Q.** Okay. But you decided to have a meeting with Dr. Borak and Dr. Holford and yourself to discuss the McGovern study; correct?





MR. COREY GORDON: Object to the form of the question.
**A.** I mean, I was told -- asked to come to a meeting to meet them. That's really what there was, and we did discuss the study, yes, very much.
**Q.** How long did you --
It was the majority of your discussions; correct?
**A.** Probably, yeah.
**Q.** Okay. And you all got together and figured out a way to discredit the McGovern study; correct?
MR. COREY GORDON: Object to the form of the question.
**A.** I don't know if I would have used that term. To look at it critically.
**Q.** To look at the study critically; correct?
**A.** Yes. Yeah.
**Q.** And let me ask you this. Prior to agreeing to be an expert in this case did you look at the McGovern study?
**A.** No. I don't think I --
**Q.** Okay.
**A.** -- knew about it.
**Q.** Did you --
Did you do any research to determine whether

17:08:32 or not you agreed with the -- with the defense in this
17:08:35 case before you agreed to be an expert?
17:08:39 **A.** I spent -- no, just a couple of days, you
17:08:42 know. So I told you the -- one thing was the timing
17:08:44 was good, it was interesting, it was a single case.
17:08:50 And I thought, well, you know, it might be interesting
17:08:53 to look at this, particularly if you're really just
17:08:57 asked to learn and they pay you to learn, and that's
17:09:01 how I thought about it.
17:09:03 **Q.** Well they didn't pay you to learn, they paid
17:09:05 you to be an expert for them in this case.
17:09:08 MR. COREY GORDON: Object to the form of
17:09:08 the question, lack of foundation, mischaracterizes
17:09:10 the evidence.
17:09:11 **Q.** It's your understanding that 3M hired you
17:09:13 just to learn?
17:09:15 **A.** 3M didn't hire me.
17:09:17 **Q.** The attorneys representing --
17:09:19 **A.** The attorneys did, yeah.
17:09:20 **Q.** And who do you think was paying the
17:09:22 attorneys?
17:09:23 **A.** 3M.
17:09:23 **Q.** Okay. So it's your opinion that 3M or the
17:09:27 attorneys hired you just to learn?
17:09:28 **A.** No. You just asked me why I sort of got





17:09:32 involved, because this is really why.
17:09:34 **Q.** Okay.
17:09:34 **A.** To get a task where you're actually
17:09:37 reviewing the literature and getting paid for it --
17:09:40 **Q.** Well --
17:09:41 **A.** -- as well, so.
17:09:42 **Q.** -- you charged $300,000 or -- in this case;
17:09:45 correct?
17:09:45 **A.** Yeah.
17:09:46 **Q.** Okay. And if you were not going to side
17:09:50 with the defendant with respect to what their position
17:09:55 is in the Bair Hugger, you would agree with me that
17:10:01 they probably wouldn't pay you $300,000.
17:10:03 MR. COREY GORDON: Object to the form of
17:10:04 the question, argumentative, lack of foundation.
17:10:07 **A.** You'll have to ask the -- you know, the
17:10:09 legal team what they would have done if --
17:10:09 **Q.** At what point --
17:10:12 **A.** -- I mean at -- at some point, if I
17:10:15 disagreed, it would be down there. I went -- As you
17:10:18 know in my report, I've tried to put down what I
17:10:20 learned, and again I'll give the phrase, read 'em and
17:10:25 weep. That's what --
17:10:25 **Q.** At what point in time did you make the
17:10:28 determination that the Bair Hugger doesn't increase





17:10:29 the risks of periprosthetic surgical -- periprosthetic
17:10:33 joint infection?
17:10:33 **A.** You talking about generally, or in the first
17:10:35 case, or what?
17:10:36 **Q.** In the life of Dr. Wenzel.
17:10:41 MR. COREY GORDON: Object to the form of
17:10:41 the question.
17:10:44 **A.** I don't know exactly when, but towards the
17:10:47 time of my report on -- on the first case I said I
17:10:51 couldn't find any information that would really link
17:10:55 that infection to the Bair Hugger. Got more
17:10:59 complicated, as you know, very quickly, and I was
17:11:03 surprised how -- how -- how the numbers grew.
17:11:07 **Q.** Assuming that the majority of periprosthetic
17:11:18 joint infections are caused by airborne contamination,
17:11:25 would that affect your opinions in this case?
17:11:27 MR. COREY GORDON: Object to the form of
17:11:29 the question, incomplete hypothetical, assumes facts
17:11:32 not in evidence.
17:11:33 **A.** It's hard for me to answer that because it's
17:11:37 not only a hypothetical, it's something that I just
17:11:38 can't find any data for. I don't agree with --
17:11:41 **Q.** I understand that.
17:11:42 But just assume, and I'm allowed to ask you
17:11:45 hypotheticals to test your -- your methodology and





17:11:47 basis.
17:11:47 **A.** Umm-hmm.
17:11:48 **Q.** Assume that a hundred percent of
17:11:54 periprosthetic joint infections are caused by airborne
17:11:57 contamination in the operating room. Would that
17:12:00 affect your opinion whether or not the Bair Hugger
17:12:03 increases the risk of periprosthetic joint infections?
17:12:06 **A.** So the data are the --
17:12:07 MR. COREY GORDON: Same objections.
17:12:08 THE WITNESS: Yeah. I'm sorry.
17:12:11 **A.** The data are the same whatever the
17:12:11 assumption is that I would base my opinion on.
17:12:15 **Q.** Well you were -- your assumption is that, I
17:12:20 think it was 80 or 90 percent of periprosthetic joint
17:12:23 infections are caused by the patient's flora.
17:12:25 **A.** That's correct.
17:12:26 **Q.** Okay. Assume that zero percent are caused
17:12:29 by the patient's flora and a hundred percent are
17:12:32 caused by contaminants in the air in the operating
17:12:34 room. Would that affect your opinion based on the
17:12:37 particle studies, Darouiche, Stocks, the neutral
17:12:42 buoyant studies of whether or not the Bair Hugger
17:12:44 increases the risk of periprosthetic joint infection?
17:12:47 MR. COREY GORDON: Same objections.
17:12:48 **A.** So for me the only clinical data you have is

17:12:52 McGovern, and I would go through the McGovern study as
17:12:58 critically as I did regardless of what assumption.
17:13:03 **Q.** Well you agree with me that -- Strike that.
17:13:09 You're aware of the Legg studies; correct?
17:13:13 **A.** Yeah.
17:13:14 **Q.** The particle and the neutrally buoyant
17:13:17 helium bubbles; correct?
17:13:18 **A.** Yeah, yeah.
17:13:19 **Q.** And that shows that when the Bair Hugger is
17:13:21 turned on particles and helium bubbles increase over
17:13:23 the surgical site; correct?
17:13:26 **A.** Yeah.
17:13:26 **Q.** Okay. And you're aware of the McGovern
17:13:29 study also did a neutrally buoyant bubble test;
17:13:32 correct?
17:13:32 **A.** Yes, I think that's right.
17:13:33 **Q.** Okay. And you're aware of the Sessler
17:13:36 study, and if you looked at the raw data it would show
17:13:37 an increase in particles.
17:13:39 MR. COREY GORDON: Object to the form of
17:13:41 the question, mischaracterizes the evidence.
17:13:44 **A.** So bubbles and particles --
17:13:44 (Interruption by the reporter.)
17:13:44 **Q.** Okay. Bubbles and particles?
17:13:44 **A.** Bubbles and particles are surrogate markers





17:13:50 for the real infection, and there were times when the
17:13:53 Bair Hugger was on where the particles went up, the
17:13:56 heat went up, the bubbles went up, yes.
17:13:59 **Q.** Okay. So assuming that airborne
17:14:05 contamination is -- Strike that.
17:14:05 Assuming that with all these studies
17:14:08 regarding increased particles, increased bubbles,
17:14:11 okay, take into consideration Stocks' particle study
17:14:15 and Darouiche's CFU study and periprosthetic joint
17:14:20 infections, and assume that periprosthetic joint
17:14:27 infections are caused by airborne contamination.
17:14:30 Would that affect your opinions in this case of
17:14:33 whether or not the Bair Hugger increases
17:14:34 periprosthetic joint infections?
17:14:35 MR. COREY GORDON: Object to the form of
17:14:36 the question, incomplete hypothetical, assumes facts
17:14:38 not in evidence.
17:14:39 **A.** It's very hypothetical, and as I've told
17:14:43 you, probably not because I would look at the McGovern
17:14:45 study as the key clinical study that you're pointing
17:14:49 to for the efficacy, or for the -- saying what you did
17:14:54 about the Bair Hugger.
17:14:56 **Q.** So if the -- if -- if the Bair Hugger...
17:15:01 Let's make it even simpler.
17:15:03 **A.** Yeah.





17:15:07 **Q.** Still the same assumption that
17:15:09 periprosthetic infections are caused by airborne
17:15:11 contamination.
17:15:12 **A.** Yeah.
17:15:12 **Q.** Okay. If the Bair Hugger increases the
17:15:15 bacterial load over the surgical site, would that
17:15:20 affect your opinion of whether or not the Bair Hugger
17:15:22 increases periprosthetic joint infections?
17:15:25 **A.** Only if I could link the CFUs to infections
17:15:30 in a straightforward way.
17:15:33 **Q.** Similar to what Darouiche did but a much
17:15:34 bigger study.
17:15:35 **A.** Much bigger.
17:15:36 **Q.** Okay. So if you could link CFUs to
17:15:41 infections and the Bair Hugger increased the CFUs over
17:15:44 the surgical site, that would affect your opinions of
17:15:47 whether or not the Bair Hugger increased the risk of
17:15:49 periprosthetic joint infections.
17:15:51 **A.** Well in this hypothetical I'd want to know
17:15:52 whether the -- whatever the assumptions were,
17:15:56 including a hundred percent of infections from the
17:15:58 air, does the Bair Hugger actually increase
17:16:01 infections.
17:16:01 **Q.** Well assume --
17:16:01 **A.** That's the key question, not bubbles or





17:16:05 particles.
17:16:06 **Q.** So are you dismissing Darouiche's article?
17:16:08 **A.** No.
17:16:08 **Q.** Okay.
17:16:09 **A.** I'd say that he said there is no causal
17:16:12 relationship that he can identify here. You need a
17:16:15 much bigger study.
17:16:17 **Q.** That's --
17:16:19 You think he said there was no causal
17:16:19 relationship?
17:16:20 **A.** I thought he -- he said that this isn't
17:16:23 definite cause-and-effect. If I'm wrong, let me see
17:16:26 it.
17:16:35 **Q.** But just so I understand, my hypothetical is
17:16:39 inaccurate because it's your opinion that 90 percent
17:16:44 of these periprosthetic joint infections are caused by
17:16:48 the patient's flora.
17:16:49 **A.** Could be.
17:16:49 MR. COREY GORDON: Object to the form of
17:16:52 the question, mischaracterizes his testimony.
17:16:54 **A.** I mean I -- I think we disagree. You know,
17:16:57 I think that if you ask me where the origin of the
17:16:59 infections are, I think it's the microbiome in a high
17:17:05 proportion of patients. It could be as high as 90.
17:17:08 **Q.** Okay. Could it be as low as 10 percent?

17:17:10 **A.** No, I don't think so.
17:17:11 **Q.** Greater than 50 percent?
17:17:14 **A.** Absolutely.
17:17:14 **Q.** Greater than 70 percent?
17:17:14 **A.** Somewhere between 70 and 90.
17:17:15 **Q.** Okay. One of your criticisms on McGovern is
17:17:59 that you look -- you state that they changed
17:18:02 antibiotics during the study period; correct?
17:18:05 **A.** That's true.
17:18:07 **Q.** Okay. Did you look at the effect of the
17:18:15 prophylactic antibiotics gentamicin plus teicoplanin
17:18:22 as compared to just a -- I guess just the gentamicin
17:18:25 that was used; correct?
17:18:26 **A.** Yes.
17:18:27 **Q.** Did you look at it's effect in other studies
17:18:29 with respect to periprosthetic joint infections?
17:18:33 **A.** The comparison, you mean, --
17:18:33 **Q.** Yeah.
17:18:35 **A.** -- in other studies?
17:18:37 No, I don't think -- I didn't see any.
17:18:38 **Q.** If other studies existed that indicate that
17:18:41 there was -- they were pretty much the same type of
17:18:43 effect on periprosthetic joint infections, would you
17:18:45 agree with me that you could remove them as a
17:18:48 confounding factor in the study?





17:18:49 MR. COREY GORDON: Object to the form of
17:18:52 the question.
17:18:52 **A.** Well, I mean, first of all, no one would
17:18:56 design a study where you're going to change three or
17:18:59 four or five things. That's background. And the
17:19:03 gentamicin, as you know, is primarily targeting
17:19:06 gram-negatives and susceptible Staph, no MRSA,
17:19:12 probably very little of the coagulation negative
17:19:15 Staph. And in, I think it was Reed's testimony, he
17:19:18 said it increased the return to hemodialysis units
17:19:24 because of course those you're going to see more renal
17:19:27 failure, increased pneumonias. And Reed at the end
17:19:35 said, you know, we're not going to go with this any
17:19:35 more. If you add the teicoplanin you're going to get
17:19:39 coagulation negative Staph and you're going to get
17:19:43 MRSA, as well Staph aureus, and, you know, in case
17:19:47 you're at a hospital where they have VRE,
17:19:51 vanc-resistant enterococcus, it's going to cover that.
17:19:54 I'm sorry. I'll take that away, it won't
17:19:56 cover that. The last one.
17:20:01 **Q.** Well I'm not really word worried about renal
17:20:04 failure here, we're talking about periprosthetic joint
17:20:05 infection.
17:20:05 **A.** No, I understand --
17:20:05 **Q.** Okay.





17:20:07 **A.** -- but there are a lot of reasons not to use
17:20:08 that.
17:20:09 **Q.** Okay. Do you know what the difference in
17:20:11 the reduction of periprosthetic infection rates
17:20:14 between the two different types of antibiotics used in
17:20:16 McGovern?
17:20:17 MR. COREY GORDON: Object to the form of
17:20:18 the question.
17:20:18 **A.** I think the --
17:20:21 Well they were either the same or might have
17:20:24 been a little higher in fact with the teicoplanin
17:20:27 gent.
17:20:27 **Q.** But do you know whether or not there was a
17:20:30 statistically significant difference --
17:20:31 **A.** Don't know.
17:20:32 **Q.** -- between -- with respect to periprosthetic
17:20:34 joint infections?
17:20:34 **A.** No. I don't remember that.
17:20:35 **Q.** Okay. So it is possible, if there's no
17:20:37 statistical significant difference between the
17:20:41 incident of periprosthetic joint infections with
17:20:42 different antibiotic regimes, it would not be a
17:20:45 confounding factor.
17:20:48 MR. COREY GORDON: Object to the form of
17:20:48 the question, incomplete hypothetical.





17:20:50 **A.** You know, I'm always going to tell you
17:20:52 things are possible.
17:20:55 **Q.** Well you're stating -- you're criticizing
17:20:57 the study because they have switched the antibiotic --
17:21:03 prophylactic antibiotics during the study period;
17:21:06 correct?
17:21:06 **A.** That's true.
17:21:06 MR. COREY GORDON: Object to the form of
17:21:07 the question.
17:21:07 **Q.** Do you have any evidence that that change in
17:21:09 the prophylactic antibiotics had an effect on the
17:21:11 infection rates of the periprosthetic joint
17:21:13 infections?
17:21:14 **A.** If you hold the antibiotics and the
17:21:17 thromboprophylaxis the same, the rates are one percent
17:21:20 and one percent. Two with the confounders.
17:21:25 **Q.** My question is: Do you have any evidence
17:21:26 that the change in prophylactics have an effect on
17:21:32 periprosthetic joint infections --
17:21:32 MR. COREY GORDON: Objection --
17:21:34 **Q.** -- in general?
17:21:36 MR. COREY GORDON: Objection, asked and
17:21:38 answered.
17:21:38 **A.** That's the best I can offer you.
17:21:39 **Q.** So you're looking at the McGovern study for

17:21:43 your opinion that the two different types of
17:21:45 antibiotic regimes have an effect on periprosthetic
17:21:49 joint infections.
17:21:50 MR. COREY GORDON: Object to the form of
17:21:53 the question.
17:21:53 **A.** I don't know that I would say it that way.
17:21:58 I don't remember exactly when you look just
17:22:00 at the antibiotic and all the other things are still
17:22:02 moving, what the rates were.
17:22:07 **Q.** Well are you -- is there any article that
17:22:11 you reviewed in your 300-some hours of literature
17:22:17 review to indicate that there is a difference in
17:22:20 infection rates between the two antibiotic regimes
17:22:24 used in the McGovern study?
17:22:25 MR. COREY GORDON: Object to the form of
17:22:26 the question.
17:22:26 **A.** No. I don't have any study I can point to
17:22:28 for that.
17:22:29 **Q.** Okay. Were you aware of -- Strike that.
17:23:20 Figure 13 you're referring to --
17:23:32 **A.** What page are you on?
17:23:34 **Q.** Oh, page 67. You're relying on what Dr.
17:23:43 Borak prepared; correct?
17:23:44 **A.** Yeah. He created the graph, so I used it.
17:23:48 **Q.** How many conversations did you have with Dr.





17:23:50 Borak and Dr. Holford?
17:23:52 **A.** Besides the meeting, not at all with
17:23:57 Holford, and one conversation with Borak.
17:24:00 **Q.** In the past year and a half?
17:24:02 **A.** The whole time that we've known each other.
17:24:05 **Q.** Okay. Did you take notes during your
17:24:10 meeting with Dr. Borak and Dr. Holford?
17:24:13 **A.** No. I don't think so -- Well I don't think
17:24:16 so, no.
17:24:17 **Q.** Okay. On page 72?
17:25:08 **A.** Okay.
17:25:08 **Q.** The highlighted section says: "In the
17:25:12 discovery phase of the trial, it has been shown that 7
17:25:15 studies showing safety of the Bair Hugger were not
17:25:17 published, were kept secret."
17:25:19 **A.** Yeah.
17:25:21 **Q.** What makes you believe that they were kept
17:25:22 secret?
17:25:25 **A.** Because they were never published. They
17:25:27 were data that were not favorable to Augustine, and
17:25:32 why didn't he publish them?
17:25:34 **Q.** That means he kept it secret?
17:25:36 **A.** That's what I think happened.
17:25:37 **Q.** So you think any study that people do that
17:25:39 they decide not to publish is kept secret?





17:25:42 **A.** No, but if you have seven that makes me
17:25:44 suspicious.
17:25:45 **Q.** Okay. So 3M has thousands of studies and
17:25:54 tests done on the Bair Hugger that they never
17:25:56 published, so are they keeping stuff secret?
17:25:59 MR. COREY GORDON: Object to the form of
17:26:00 the question, assumes facts not in evidence.
17:26:02 **A.** I don't know how to answer that. I mean,
17:26:04 what kind of studies are we talking about, were they
17:26:07 comparis -- looking for harm?
17:26:10 **Q.** Computational fluid dynamic studies.
17:26:12 **A.** I don't know.
17:26:13 MR. COREY GORDON: Same objections, also
17:26:14 lack of foundation.
17:26:15 **Q.** Schlieren studies.
17:26:17 You know what Schlieren is?
17:26:19 **A.** No.
17:26:19 **Q.** Calculations of whether or not the Bair
17:26:21 Hugger disrupts laminar flow. Have you seen those?
17:26:23 **A.** No.
17:26:24 **Q.** Okay. So are they keeping all their studies
17:26:33 secret?
17:26:33 MR. COREY GORDON: Object to the form of
17:26:35 the question, assumes facts not in evidence, --
17:26:38 **A.** I don't know.





17:26:37 MR. COREY GORDON: -- lack of foundation.
17:26:43 **Q.** Have you ever met Dr. Scott Augustine?
17:26:52 **A.** Doctor who?
17:26:53 **Q.** Scott Augustine?
17:26:54 **A.** No, I haven't.
17:26:57 **Q.** Do you have an opinion of Dr. Scott
17:26:59 Augustine?
17:27:00 MR. COREY GORDON: Object to the form of
17:27:02 the question.
17:27:02 **A.** As -- In what way, opinion as to --
17:27:04 **Q.** As an inventor, as a doctor?
17:27:07 **A.** Well he's creative, obviously. The guy, you
17:27:08 know, invented the Bair Hugger and I -- I would say
17:27:11 he's a real entrepreneur. I have a lot of criticisms
17:27:15 of his most recent study, if that's what you mean.
17:27:19 **Q.** That's not in your report, is it, sir?
17:27:20 **A.** No.
17:27:34 **Q.** Okay. Do you have any criticisms of the
17:27:35 HotDog device?
17:27:38 **A.** Of the device itself?
17:27:40 **Q.** Yeah.
17:27:41 **A.** I'm not aware -- No, I...
17:27:43 No, I don't.
17:27:45 **Q.** And you've seen studies that show that the
17:27:46 HotDog is just as efficacious as the Bair Hugger in

17:27:50 orthopedic surgeries.
17:27:52 **A.** I haven't seen that. But what it show -- if
17:27:55 you're talking about particles or stuff like that?
17:27:58 **Q.** I'm talking about efficacy of warming
17:28:00 patients.
17:28:00 **A.** No. There -- I don't think there are any
17:28:02 data.
17:28:26 **Q.** Now is it my understanding that you would
17:28:29 need a clinical study to -- Strike that.
17:28:36 If a device contaminates the sterile field,
17:28:43 you would need a clinical study to show that it caused
17:28:45 harm?
17:28:46 MR. COREY GORDON: Object to the form of
17:28:48 the question, incomplete hypothetical.
17:28:52 **A.** I would say that would be a signal that
17:28:56 would lead to a study that we would see whether or not
17:29:00 that signal with, let's say, particles equate to
17:29:05 infection, and that's what I would want to have.
17:29:30 **Q.** All right. You're a member of the
17:29:41 International Society For Infectious Disease; correct?
17:29:43 **A.** That's true.
17:29:44 **Q.** Are you still a member?
17:29:45 **A.** Yeah. You're a kind of a member forever.
17:29:47 **Q.** Okay.
17:29:47 (Wenzel Exhibit 13 marked for





17:29:47 identification.)
17:29:47 BY MR. ASSAAD:
17:30:01 **Q.** Do you recognize this document?
17:30:03 **A.** I do.
17:30:04 **Q.** It's titled, "A Guide to Infection Control
17:30:06 in the Hospital, Fourth Edition"; correct?
17:30:09 **A.** Yes.
17:30:09 **Q.** And you're the editor; correct?
17:30:11 **A.** Yes.
17:30:11 **Q.** And we discussed this doc -- we discussed
17:30:13 this book before; correct?
17:30:14 **A.** We did.
17:30:15 **Q.** Okay. And you had --
17:30:19 And you believe this is authoritative;
17:30:20 correct?
17:30:21 **A.** Yeah, with the context I gave you what we're
17:30:24 trying to do in poor countries where the resources are
17:30:29 just limited, we tried to come up with some key points
17:30:32 for healthcare workers.
17:30:34 **Q.** Are you saying this only applies to poor
17:30:35 countries and not to the United States?
17:30:37 **A.** No, but that was the major -- that was the
17:30:38 major thrust.
17:30:40 **Q.** But I would hope that you would treat, like,
17:30:43 Third World countries the same as you would First





17:30:45 World countries.
17:30:45 **A.** I would.
17:30:46 MR. COREY GORDON: Object to the form of
17:30:47 the question.
17:30:48 **Q.** So I want to turn to Chapter 21. I only
17:30:52 printed up Chapter 21.
17:30:57 **A.** Yes.
17:30:59 **Q.** Let's look at page -- paragraph on the
17:31:04 bottom of page 134 that starts with "exogenous"?
17:31:07 **A.** Okay.
17:31:08 **Q.** And this is --
17:31:10 And you reviewed this before; correct?
17:31:11 **A.** I did see this.
17:31:12 **Q.** And you approved this for publication;
17:31:13 correct?
17:31:13 **A.** I did.
17:31:14 **Q.** Okay. "Exogenous contamination of wounds is
17:31:17 also important in the pathophysiology of SSIs,
17:31:21 particularly for clean surgical procedures."
17:31:23 Did I read that correctly?
17:31:24 **A.** Yes.
17:31:24 **Q.** And a clean surgical -- a clean surgical
17:31:27 procedure would be a total hip or total knee
17:31:30 arthroplasty; correct?
17:31:31 **A.** That's correct.





17:31:32 **Q.** "Airborne bacteria originating from the
17:31:34 patient or the surgical team suffice to create SSI in
17:31:38 these types of procedures, particularly when implants
17:31:41 are being placed (example, total hip prostheses)."
17:31:44 Did I read that correctly?
17:31:46 **A.** You did.
17:31:46 **Q.** Okay. Those are the surgeries that are at
17:31:48 issue in this case; correct?
17:31:49 **A.** Yes.
17:31:49 **Q.** Okay. Airborne contamination well well
17:31:53 affect other clean surgical procedures with long
17:31:55 exposure times and large surface areas, period.
17:31:58 Correct?
17:31:58 **A.** Yes.
17:31:59 **Q.** "The main source of airborne bacteria in the
17:32:01 OR originate primarily from the skin of individuals in
17:32:04 the room," period.
17:32:05 Did I read that correctly?
17:32:06 **A.** You did.
17:32:13 **Q.** "The number of persons present in the OR as
17:32:16 well as their level of activity, the type of surgery,
17:32:19 the quality of air provided, the rate of air exchange,
17:32:22 the quality of staff clothing, the quality of cleaning
17:32:26 process and the level of compliance with infection
17:32:27 control practices all influence airborne

17:32:31 contamination," period.
17:32:32 Did I read that correctly?
17:32:33 **A.** You did.
17:32:34 **Q.** And this is something that you agreed with
17:32:35 at the time that it was published; correct?
17:32:37 **A.** Agreed that, yes.
17:32:39 **Q.** Okay. "Although these may seem trivial
17:32:44 issues for contaminated procedures or dirty
17:32:46 procedures, they are very important to consider in
17:32:49 clean and clean-contaminated surgery," period.
17:32:52 Did I read that correctly?
17:32:53 **A.** You did.
17:32:53 **Q.** And that's something that you yourself as
17:32:55 the -- the main editor, published in 2008; correct?
17:33:00 **A.** We did.
17:33:02 MR. ASSAAD: I have no more questions.
17:33:04 MR. COREY GORDON: I'll just have a couple.
17:33:04 EXAMINATION
17:33:04 BY MR. COREY GORDON:
17:33:06 **Q.** Keep Exhibit 13 open. That paragraph that
17:33:09 counsel was just reading from in that sec -- Go back
17:33:15 to page 134.
17:33:17 **A.** Sure.
17:33:19 **Q.** Under **"Known Facts**."
17:33:22 **A.** Yes.





17:33:22 **Q.** Could you just read the first sentence,
17:33:24 please?
17:33:25 **A.** "Most SSIs arises from the patient's
17:33:28 endogenous flora which contaminate the wound by direct
17:33:31 contact."
17:33:32 **Q.** Thank you.
17:33:33 And if you could turn to page 138?
17:33:39 **A.** Yeah.
17:33:39 **Q.** And could you -- in the -- just read that
17:33:42 first paragraph under **"Controversial Issues"** there.
17:33:44 **A.** "ORs equipped with laminar airflow system
17:33:48 provide almost sterile air, yet a very few studies
17:33:52 show a significant decrease in SSI rates for surgical
17:33:56 procedures performed in this type of OR."
17:34:01 **Q.** And go ahead and read the rest of the
17:34:03 paragraph.
17:34:03 **A.** "Furthermore, some of these experiments did
17:34:06 not control for the antimicrobial regimen received as
17:34:10 surgical prophylaxis, thus precluding any conclusion
17:34:13 on the exact role of the laminar flow system.
17:34:16 Therefore, at this time no recommendation can be made
17:34:19 for the use of laminar flow ventilation in" the "ORs."
17:34:25 **Q.** This was published in 2008; is that right?
17:34:31 **A.** I think that's right. Yes.
17:34:33 **Q.** Thank you.





17:34:33 MR. COREY GORDON: I have nothing further.
17:34:34 MR. ASSAAD: I have one more question.
17:34:34 EXAMINATION
17:34:34 BY MR. ASSAAD:
17:34:39 **Q.** Go to page 134.
17:34:40 **A.** Oh, okay.
17:34:47 **Q.** When you read, "Most SSIs arise from the
17:34:49 patient's endogenous flora which contaminate the wound
17:34:52 by direct contact." "Direct contact" is -- is by --
17:34:56 by hand or some inanimate device; correct?
17:35:00 **A.** When I think of it I think that it's already
17:35:03 there, as you know, we've talked about this before,
17:35:05 and once the blade goes across that's direct contact
17:35:09 with the wound. Now she may mean, in addition, you
17:35:13 know, if there's a -- a scalpel that picks up part of
17:35:17 the flora and then is used in the wound. I would have
17:35:21 to go back and talk to her if -- what she meant more
17:35:25 commonly, or both.
17:35:26 **Q.** But you understand bacteria -- when they
17:35:29 talk about direct contact with bacteria, it's
17:35:31 transferring it from, like, your hand to a device or
17:35:33 your hand to a wound; correct?
17:35:35 **A.** That's correct.
17:35:37 MR. COREY GORDON: Object to the form of the
17:35:37 question.





17:35:37 MR. ASSAAD: That's all I have.
17:35:38 THE WITNESS: Okay.
17:35:38 MR. COREY GORDON: We're done. We'll read
17:35:40 and sign.
17:35:43 THE REPORTER: Off the record.
17:35:44 (Deposition concluded at 5:35 p.m.)

C E R T I F I C A T E

I, Debby J. Campeau, hereby certify that I am qualified as a verbatim shorthand reporter; that I took in stenographic shorthand the testimony of RICHARD P. WENZEL, M.D., MSc., at the time and place aforesaid; and that the foregoing transcript consisting of 368 pages is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Lino Lakes, Minnesota, this 9th day of August, 2017.

DEBBY J. CAMPEAU
Notary Public





S I G N A T U R E P A G E

I, RICHARD P. WENZEL, M.D., MSc., the deponent, hereby certify that I have read the foregoing transcript, consisting of 368 pages, and that said transcript is a true and correct, full and complete transcription of my deposition, except per the attached corrections, if any.

| PAGE | LINE | CHANGE/REASON FOR CHANGE |
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_____ _____
Date Signature of Witness

WITNESS MY HAND AND SEAL this _____ day of _____, 2017.

(DJC) _____